A STUDY TO ASSESS THE EFFECTIVENESS OF HELFER SKIN TAP TECHNIQUE ON PAIN REDUCTION AMONG INFANTS UNDERGOING INTRAMUSCULAR VACCINATION IN TERTIARY CARE SETTING, COIMBATORE

By

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ABSTRACT

A study to assess the effectiveness of Helfer skin tap technique on pain reduction among infants undergoing intramuscular vaccination in tertiary care setting, Coimbatore.

Background of the study: Pain is a common and disagreeable sensation for children and adult. Every child has his or her own perception of pain. Routine immunizations are the most frequent painful medical procedure during childhood. Health care professionals trying to provide vaccine to the infants with a less painful experience at their level of comfort, skin tapping (Helfer skin technique) is one of the methods which keeps the muscles relaxed and thus reduce pain while administering IM vaccination.

Objectives of the study: To assess the effectiveness of Helfer skin Tap technique on pain reduction among infants undergoing intramuscular vaccination and to associate the selected demographic variables with the pain level of infants during intramuscular vaccination among treatment and routine group.

Methodology: The research design adopted was quantitative research approach, quasi experimental, time series design. The study was conducted in pediatric vaccination clinic in PSG Hospitals, Peelamedu, Coimbatore. Purposive sampling technique used to select the eligible population. Simple random sampling technique was used to allocate the 60 study subjects to treatment and routine group which comprised 30 in each group. FLACC pain scale was used to assess the vaccination pain among infants undergoing intramuscular vaccination. Pre assessment was done 5minutes prior to the administration of IM vaccination for both groups and Helfer skin tapping was given to infants of treatment group. During Intramuscular vaccination the pain assessment was done in both the groups and post test level of pain was assessed at 1, 5, and at 10 minutes using FLACC pain scale.

Results: The study findings high lights that during pre assessment in treatment group 27(90%) infants were relaxed and comfortable & in routine group 23 (76.77%) infants were relaxed and comfortable. During vaccination in treatment group 19(63.33%) infants experienced moderate pain where as in routine group 27(90%) infants experienced severe pain. After the vaccination at 1st minute the treatment group 18(60%) infants had moderate pain where as the routine group 12(40%) infants had severe pain. Five minutes after the vaccination in treatment group 15(50%) infants had mild pain where as in routine group 14(46.6%) infants had moderate pain. Ten minutes After the vaccination in treatment group 26(86.6%) infants relaxed and comfortable where as in routine group 24(80%) infants experienced mild pain. There was a significant reduction in pain perception among infants in treatment group during vaccination (5.30 ± 1.74,$p<0.001$), after the vaccination at 1stminute(3.93 ± 1.51,$p<0.001$) and 5thminute (2.03 ± 1.69,$p<0.001$) and at 10th minute (0.39 ± 0.79, $p<0.001$)than the routine group. Female infants 15(50%) experienced severe pain compared with male infants 12(40%) in routine group ($\chi2=6.44$,$P<0.01$).For other demographic variables there was no association in treatment and routine group.

Conclusion:. Helfer skin tap technique was effective in reducing the IM vaccination pain during and after the vaccination.

Key words: Infants, Helfer Skin tap technique, pain, FLACC pain scale, penta and easy six vaccine.

CHAPTER I

INTRODUCTION

1.1 Background of the study

Child survival is a field of public health concerned with reducing child mortality. Child survival interventions are designed to address the most common causes of child deaths that occur, which include communicable diseases. Among children under the age of 5 alone, an estimated 5.6 million children die each year mostly from such preventable causes. In developing countries, child mortality rates related to communicable disease reduced by introducing low-cost immunization**. (UNICEF, 2017)**

Infant mortality rate was an indicator used to monitor progress towards the Fourth Goal of the Millennium Development Goals**.** The prevalence of infant mortality rate globally as reported as 4.2 million. In India it was 37.8 per 1000 live birth. Diphtheria contributed to 20% infant death, pertussis contributed to 2% fatal illness and 70-80% death occurs globally due to Tetanus among children who are unvaccinated**. (WHO, 2017)**

Vaccinations are the safest and most effective way to prevent serious illness and death. In fact, vaccinations prevent approximately 2.5 million deaths every year. However, despite the success of vaccinations in preventing morbidity and mortality, some countries struggle to maintain high levels of vaccination update. For example, in 2016 only 69% of Indian children aged 19–35 months had fully completed a combined series of childhood vaccinations**. (WHO, 2016)**

The Centers for Disease Control and Prevention recommends vaccinations to prevent 17 life-threatening diseases; consequently, adherence to the recommended vaccination schedule means children will receive an average of 18–24 injections by the time they are 2 years old. Adherence to the vaccination gives protection against so many diseases. Some parents may delay or refuse childhood vaccinations for a variety of reasons. A few of the common parental reasons for refusing childhood vaccinations include questioning vaccination safety, distrust of the government, concern about contraindications with a child's underlying medical condition, as

well as the pain and anxiety associated with needle puncture. (**Centers for Disease Control and Prevention, 2016)**

Intra muscular injection is common yet a complex technique used to deliver medication and vaccination deep into the large muscles of the body. Intra muscular injection route provides faster drug absorption than the subcutaneous route because the muscle has grater vascularity. There are several factors which influence person experience of pain during Intra muscular injection for example anxiety, culture, age, gender, and expectation of pain relief. These factor may increase or decrease perception of pain during intramuscular injection. **(Taddio A, Shah V, Leung E, et al., 2015)**

A pain producing stimulus sends an impulse across a peripheral nerve fiber. The pain fiber enters the spinal cord and travels one of several routes until ending within the gray matter of the spinal cord. There the pain message interacts with inhibitory nerve cells and preventing the pain stimulus from reaching the brain to the cerebral cortex. Once a pain stimulus reaches the cerebral cortex the brain interprets the quality of pain and processes information about past experience, knowledge and cultural associations in the perception of pain**. (Wise E .A ,et al., 2013)**

Injection for vaccination, the most common source of iatrogenic pain in childhood .It is administered repeatedly to almost all children throughout infancy, child hood and adolescence. The pain associate with such injections is a source of distress for children, their parents and those administering the injection. If not addressed, this pain can lead to pre procedural anxiety in the future, needle fear and health care avoidance with vaccination schedules. It is estimated that up to 25% of adult have a fear of needles, with most fear developing in childhood. About 10% of population avoids vaccination and other needle procedure because of pain**. (Sparks L et al., 2013**)

Helfer skin tap technique is tapping over the intramuscular site with the palmer aspect of finger 16 times before and the 3 counts during the procedure. Skin tapping in the area close to the site of an immunization injection will activate A- beta neuron which will close the gate. Transmission of pain signals arising from the injection site will, therefore, be inhibited at the

level of the spinal cord. The proximity of tapping and injection site would be expected to facilitate gating for the appropriate spinal neurons**. (Fishman S, Ballantyne j, Bonica JJ, 2014)**

Innovative Evidenced Based Nursing interventions for minimizing pain during child hood vaccination can help to prevent distress, development of needle fear and subsequent health care avoidance behaviors such as non adherence with vaccination schedule. Most positive experience during vaccine injection also maintains and promotes trust in health care providers (**Taddio A, Chambers CT, Halperin SA, 2014)**

1.2 Need for the study

Pain is a common and an existing sensation for children and adult. Every child has his or her own perception of pain. (**Mcgrath pain in children, 2014**)

Routine Immunization is the most frequent painful medical procedure during childhood. The world health organization estimates that 12 billion injections are given annually and out of which approximately 5% are childhood vaccination. Vaccine injections are the most common reason for iatrogenic pain in childhood. With the steadily increasing number of recommended vaccination, there has been a concomitant increase in concern regarding the adequacy of pain management**. (Taddio A, chamber CT, 2014**)

A fundamental principle of responsible medical care is not 'do not hurt' but 'do not harm' since pain is harmful to children, the care givers are committed in preventing harm to their patients**. (Ball J W, Binder C, 2015**)

A descriptive study was conducted to examine the relationship between a mother rating her own and child's anxiety prior to an immunization. Eighty three pre-school children and their mother attended vaccination clinic to receive an immunization were included as sample. Each mother was asked to rate how anxious she and her child were prior to the immunization using separate 5-point behavioral scales. The result of the study showed that anxiety of mother and children was significantly higher prior to the procedure. (**Broome ME, 2013)**

An experimental study was done in Canada to assess the effectiveness, feasibility and parental acceptance of a sample combination pain reduction intervention of infants receiving multiple immunizations. One hundred and sixteen infant and parents participated. The

intervention group received sucrose and oral tactile stimulation and were held by their parents during immunization .The median (25^{th} -78^{th} percentile range) first cry duration was 19 seconds for the intervention group reported a strong preference for future use of pain reduction technique for injection procedure. **(IPP Morhe, 2015)**

DPT vaccine generates more pain due to the presence of an inactivated whole cell component of pertussis. Most Whole cell Pertussis vaccines are available in combination with diphtheria (D) and tetanus (T) vaccines, contain aluminum salts as an adjuvant and, thiomersal as a preservative. Immunization with Whole cell Pertussis vaccines is effective and inexpensive than a cellular pertussis. (**Asha, 2016)**

Although health care providers usually consider vaccinations to be a benign procedure requiring little intervention, immunization are the most common painful, stressful experience and anxiety producing procedures for children as well as parents to take place in the health care settings. **(Brady K, Avner JR, Khine H, 2014)**

Providing pain relief is considered a most basic human right, so it is the responsibility of the nurse to use most effective approach to pain control. Nurses are ethically and legally responsible for managing pain and reliving suffering. Effective pain management not only reduces physical discomfort, but also improves quality of life.

Helfer skin tap technique offers a painless injection experience. It provides a mechanical stimulation and distraction during intramuscular injection and thus helps to decrease pain as described in gate control theory. In Helfer skin tap technique rhythmic tapping before injection over the skin at the site of injection keeps the muscle relaxed and stimulates large diameter fibers. **(Malkin, 2008)**

The investigator during her clinical experience observed the level of pain among children when the routine vaccination is being given. So she was indented to apply this technique.

Considering all the above facts motivated the investigator to conduct this study to determine the effectiveness of Helfer skin tap technique on reducing vaccination pain in infants those who are receiving Penta and Easy Six vaccines.

1.3 Statement of the problem:

A Study to Assess the Effectiveness of Helfer Skin Tap Technique on Pain Reduction Among Infants Undergoing Intramuscular Vaccination in Tertiary Care Setting, Coimbatore.

1.4 Objectives

- To assess the pain level of infants receiving intramuscular vaccination in routine group and treatment group.
- To compare the pre and post test level of pain during intramuscular vaccination among infants in routine and treatment group.
- To compare the pain level of infants during intramuscular vaccination between routine group and treatment group at various time intervals.
- To associate the selected demographic variables with the pain level of infants among treatment and routine group.

1.5 Assumption

- Every child is unique and responds in an unique way to painful procedure.
- Relaxation of the muscle may reduce the vaccination pain.

1.6 Hypothesis

- **H_1:** there will be a significant difference in the pretest and post test level of pain during intramuscular vaccination among infants in routine and treatment group.
- **H_2:** there will be a significant difference in the pain score at various time intervals between routine and treatment group.
- **H_3:** there will be a significant association between the pain level of infants and selected demographic variables during intra muscular vaccination.

1.7 Delimitations

The study is delimited to:

- Infants aged 6-14 wks who undergo intramuscular vaccination.

- Infants who receive penta (Diphtheria, Pertussis, Tetanus, Hepatitis, Haemophilus influenza) and easy six vaccine((Diphtheria, Pertussis, Tetanus, Hepatitis, Haemophilus influenza, inactivated polio vaccine).
- Only in vaccination clinic.

1.8 Operational definition

Effectiveness:

Effectiveness refers to the reduction of pain in infants influenced by Helfer skin tap technique during intramuscular vaccination as measured by FLACC pain scale.

Helfer skin taps technique:

Tapping over the intramuscular injection site with the palmer aspect of finger 16 times before and 3 counts during the administration of penta vaccine and easy six vaccination to an infants and continue the tapping till needle is removed.

Pain:

It refers to the behavioural expression of an infant during and after intramuscular vaccination as measured by FLACC pain scale by the investigator.

Intra muscular vaccine:

It refers to administration of penta vaccines (Diphtheria, Pertussis, Tetanus, Hepatitis, Haemophilus influenza) and easy six vaccines (Diphtheria, Pertussis, Tetanus, Hepatitis, Haemophilus influenza, inactivated polio vaccine) into the vastus lateralis muscles of right lateral thigh of infants.

Infants:

Refers to the children with the age group between 6-14weeks ($1^{1/2}$-$3^{1/2}$months) undergoing intra muscular vaccination in PSG hospital, Coimbatore.

1.9 Projected outcome:

The findings of the study will help to implement the Helfer skin tap technique as an effective pain control measure by the health care personnel during IM vaccination among infants to alleviate pain and discomfort.

1.10 Conceptual framework:

Conceptualization is the process of forming ideas, designs and plans. A conceptual framework deals with the concepts assembled together by virtue of relevance to the research problem, which provides a certain frame of reference for clinical practice, research and education.

Modified Widenbach's helping art of clinical nursing theory:

Conceptual framework for this study was derived from modified Widenbach's helping art of clinical nursing theory (Fawcett, 1970). This study was based on the concept that the use of Helper skin tap technique to reduce the intramuscular vaccination pain among infant. The investigator adopted the modified Wiedenbach's helping art of clinical nursing theory as a base for developing the conceptual framework. Ernestine Widenbach's proposed a prescriptive theory for nursing, which is described as conceiving of deciding the solution and the way to attain it. It directs action towards an explicit goal. This theory has three factor:

- Central purpose
- Prescription
- Realities

Central purpose: It refers to what the nurse wants to accomplish. It is the overall goal towards which a nurse strives. In this study the main central purpose is to assess the effectiveness of Helfer skin tap technique on pain reduction among infants under going intramuscular vaccination.

Realities: It refers to the physical, physiological, emotional and spiritual factors that involves in nursing actions. In this theory there are four realities. They are as follows:

Frame work: It refers to the place in which it is practiced. Here it refers to the place where the study was conducted in vaccination clinic at PSG Hospital.

Agent: One who directs all action towards the goal and has capacities, capabilities, commitment and competence to provide care. In this study agent is nurse and researcher. The nurse who have the knowledge on vaccines and skill in administering the vaccine. The researcher who directs all

the action towards the goal including researcher knowledge & skill in Helfer skin tap technique &pain assessment.

Recipient: One who is vulnerable and dependent and receive all attention. Here the infants (6-14weeks) those who are undergoing intramuscular administration of Penta and Easy Six vaccinations are the recipient of Helfer skin tap technique.

Means: The means is the prescription for care which the nurse develop on her central purpose

Which is implemented in the realities of the situation .In this study the means is Helfer skin tapping technique through which the researcher achieve the goal.

Goals: It refers to the desired outcome of the action. Reduction in the level of pain is considered as the goal of the study.

Wiedenbach's nursing practices consists of identification, ministration and validation.

Identification: It refers to the viewing the individual's unique experiences and perceptions. In this study prevalence of level of pain was assessed by using demographic data and FLACC pain scale

Ministration: This step involves provision of required help for the identified need. The Helfer skin tap is given over the intramuscular injection site with the palmer aspect of finger 16 times before and 3 counts during the procedure and continue the tapping till the needle is removed among infants undergoing intramuscular vaccination.

Validation: It refers to measure the level of pain through the FLACC pain scale. Here the pain level of infant was assessed for during the procedure of administering vaccination and post assessment for 1^{st} minute, 5^{th} minutes, and 10th minutes after intramuscular vaccination in infants by using FLACC Pain Scale.

Summary:

This chapter dealt with background of the study, need for the study, statement of the problem, objectives, assumption, hypothesis, delimitation, operational definition, projective outcome and conceptual framework. It helps the researcher to formulate the objectives and carry out the research study accordingly. The next chapter is organized as follows:

Chapter II - Review of Literature

Chapter III - Materials and Methods

Chapter IV - Data analysis and Interpretation

Chapter V - Result and Discussion

Chapter VI -Summary and Conclusion

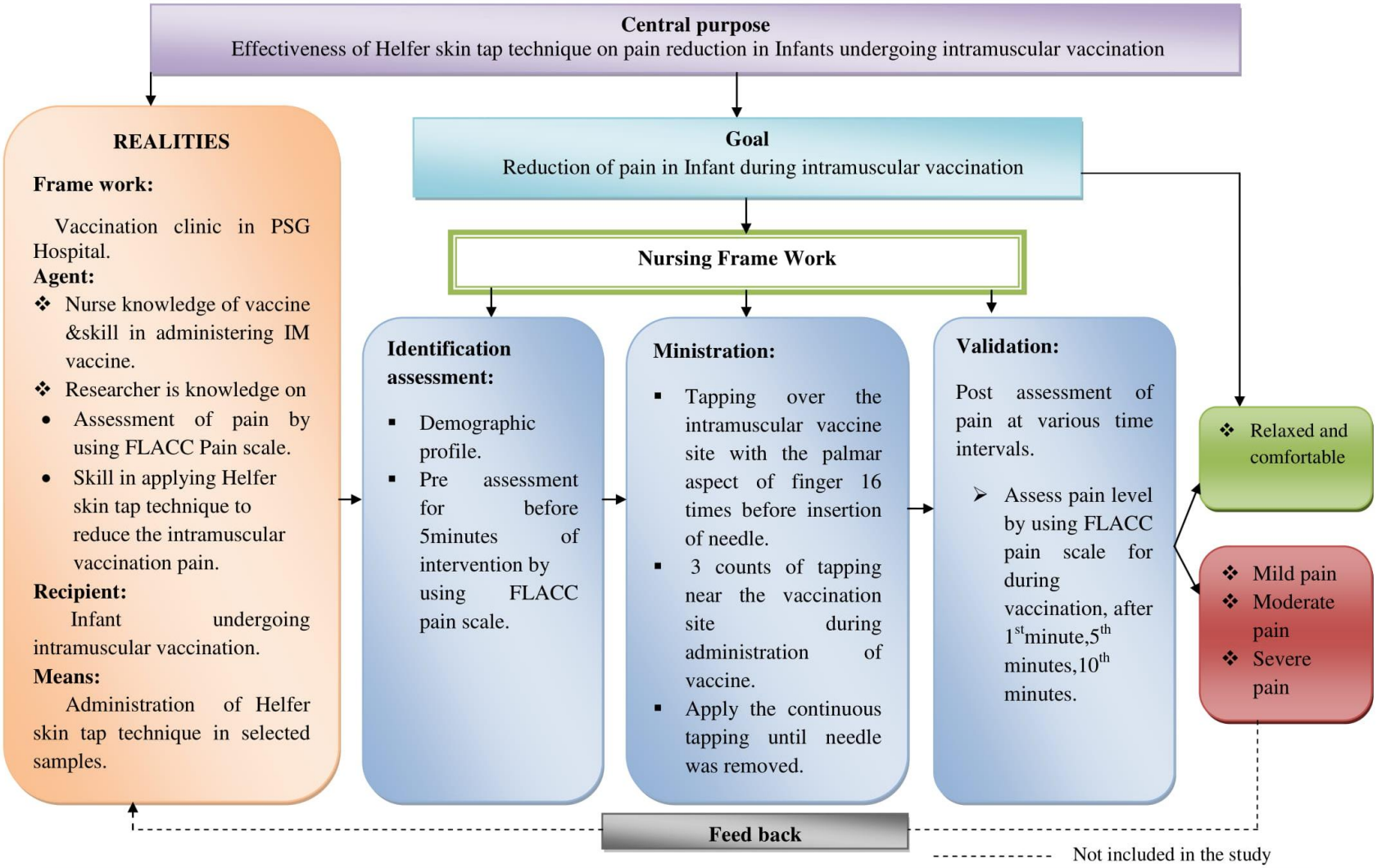

Figure 1.1 Modified Wiedenbach's prescriptive theory to assess the effectiveness of Helfer skin tap technique on pain reduction

CHAPTER -II

REWIEW OF LITERATURE

Review of literature is key a step in research process. A typical purpose of reviewing literature is to generate research question in order to identify what is known about the topic. The major goal of the review of literature is to develop a strong knowledge base to carry out research and non research scholar activities. A literature review gives an overview of what has been said, who the key writers are, what are the prevailing theories and hypotheses and what methodologies appropriate and useful. (**Burns N, 2007)**

The review of literature for this study is organized in the following headings:

2.1. The pain experience of the children undergoing immunization.

2.2. Effectiveness of various interventions on reduction of Intramuscular vaccination pain in children.

2.3. Effectiveness of Helfer skin tap technique in reducing pain perception of clients undergoing Intramuscular injection.

2.1. Reviews related to the pain experience of children undergoing immunization.

A descriptive, survey was conducted in the child health center in Canada to find the pain response among 100 children (3-15yrs) undergoing intramuscular vaccination. The result revealed that the two third of children (M±SD=6.1±2.9) and one-quarter of adolescent acknowledged some degree of needle fear (M±SD=4.34±1.78). Furthermore, 5% of parents reported avoiding or delaying their child's immunization due to their child's needle fear. Parents trusted information provided by physicians, making family physicians an important source of information for pain management. **(Taddio, 2016)**

A randomized control trail was conducted in Canada to assess the pain response of infant during immunization using a slow standard of care injection verses rapid pragmatic technique among 113 infants(4-6months).The intervention given for slow standard of care group was slow aspiration prior injection then slow withdrawal. In pragmatic group, no aspiration done and

rapidly inject the vaccine and withdraw the needle. Immediately infant pain was measured by the modified behavior pain scale (MBPS) and visual analogue scale. The study result reveals that mean of MBPS score was higher for standard group (M±SD=6.21±2.7) compared to pragmatic group (M±SD=4.61±2.45,t=7.8,p<0.00l). **(Mukash k, 2016).**

An observational study was conducted to assess the Acute pain response in infants in multidimensional description in Adelaide, Australia. Fourteen infants who were undergoing routine immunization were studied from a multidimensional perspective. The measures of data observed were heart rate, crying, body movement, posturing and voice spectrograph and pain level measured by visual analogue scale. There was wide variability between infant on the measures, especially on the cry spectrographs, although facial expression was consistent across infants. The study result shows that in initially the heart rate was dropped (90beats/mit), a long, high pitched cry followed by a sharp increase in heart rate (160beats/mit). Low pitched, but dysphonated cries, less body rigidity, but still facial expression was of pain. Finally in the second half of the minute response, heart rate remind elevated(170beats/mit) , cries were lower pitched, more rhythmic, with a rising -falling pattern, and were mostly phonated, and body posturing returned to normal. It was suggested that facial expression may be consistent across-infant indicator of pain (M±SD=7.4±3.1). **(Johnston Celeste C, Mary Ellen, 2016).**

An experimental study was conducted in Turkey to compare pain response of children who receive intramuscular vaccination (IM vaccination in deltoid muscle versus the pain response of those who receive IM vaccination in the vastus lateralis). A total of 185 infant were randomly assigned to one of the two study groups. The deltoid group and the vastus lateralis group were vaccinated respectively in the deltoid muscle and the vastus lateralis. The result indicated that pain response of infant was similar in each group. Crying duration of children who received the vastus lateralis(M±SD=3.56±1.95) vaccination was shorter than that of the deltoid group (M±SD=5.6±1.93) procedure**. (Celeblugiea A, et al., 2015)**

An observational study was done in Australia to determine infant pain response during immunization injection and the proximal influences of parental and nurse coping statement with in treatment. Pain responses in 93 infants receiving an immunization injection were video recorded and coded using the Neonatal Facial coding System (NFCS) and duration of crying was

recorded. Parent and nurse vocalization were coded using the Child-Adult medical procedure interaction Scale. A Multiple regression analysis evaluated the influences on NFCS scores, found parental coping-promoting statement in the 30 second period before the injection to have the moderate effect on facial pain response(M±SD=5.64±2.6) and during immunization infants had strongest facial pain effect(M±SD=7.64±3.6)The finding suggest that parental behavior in the treatment room has a key role in influencing how infants responds to painful procedure ($t=6.7$, $p<0.05$)**.(Piira T, Champion-D, Bustoso T,2014).**

An experimental study was conducted to determine the order of vaccine Injection and Infant Pain Response in outpatient pediatric clinic in Toronto, Ontario, Canada. Randomized clinical trial was used. A total of 120 infants participated and received the DPTaP-Hib vaccine first and 60 received the PCV first. Infant characteristics did not differ between groups. Overall mean (SD) pain scores per infant after receiving both vaccine injections were significantly lower when DPTaP-Hib was administered first compared with when PCV was administered first (MBPS score, 7.6 [1.5] vs 8.2 [1.5], P=.037; parent VAS score, 4.2 [2.3] vs 5.6 [2.6], P=.003). When given first, the DPTaP-Hib vaccine caused significantly less pain (P<0.001) than the PCV, as assessed by the MBPS, VAS, and crying**.(Patricia C. Parkin ,2014)**

A Randomized controlled trial was undertaken to assess the effects of age, gender and holding on pain response during infant immunization in pediatric health center, Canada. Infants aged 2 to 6 months were positioned either supine (SUP) on the examination table or held (HLD) by a parent during routine immunization in a community pediatric office. There was no difference between the SUP (M±SD=4.16±1.9) and HLD(M±SD=4.15±1.89) infants in duration of crying, facial grimacing or visual analogue scale (VAS) pain scores. Similarly gender did not affect pain response. In contrast, 2-month-old infants displayed more pain during immunization than did 4 or 6-month-old infants**. (Taddio A , Goldbach M, 2014)**

A Randomized control trial was conducted in an urban primary care pediatric practice in Toronto, Canada. Healthy infants 4–6 months of age were randomly allocated to intramuscular injection with DPTaP-Hib vaccine using either the standard technique or the pragmatic technique. The infants enrolled, 50 were randomized to the standard group and 50 to the pragmatic group. For the standard technique the needle was inserted at 90 degrees with steady

pressure and aspiration was performed for 5–10 seconds. The vaccine was slowly injected over 5–10 s and the needle was then slowly withdrawn. For the pragmatic technique, the needle was inserted at 90 degrees with steady pressure. No aspiration was performed and the vaccine was rapidly injected over 1–2 s and the needle then rapidly withdrawn. The entire vaccine procedure was video recorded. The infant pain response was assessed using the Modified Behavioral Pain Scale (MBPS). The result reveals that Immediate pain was greater for the standard versus (M±SD=7.4±3.2) pragmatic groups (M±SD=4.32±2.1,t=6.4,p<0.001). Infant sex had no significant effect on MBPS scores (p = 0.91). **(Anna Taddio, Jonathan Sam, 2013)**

2.2 Reviews related to effectiveness of various interventions on reduction of Intramuscular vaccination pain in children

An experimental study was conducted to determine the effectiveness of tactile stimulation on pin prick pain among infant during immunization in primary health center in Mumbai. The pain level was measured by Modified Behavioral Pain Scale (MBPS). A total of 212 infants receiving DTaP-IPV-Hib and PCV immunization were randomly assigned to two groups of 106 patients each. During the injection procedure multiple blunt plastic pins are pressed on to the skin at the injection site prior and during the penetration of the injection needle into the skin. There was an significant reduction of pain in the treatment group compared with control group after immunization (Modified Behavioral Pain Scale (MBPS): (5.16±1.37 v/s 1.90±1.27).This study explored the effect of tactile stimulation over the skin on pain reduction during immunization. **(Romanò CL, Cecca E, 2015)**

An experimental study was conducted to know the effectiveness of applying manual pressure to reduce pain during intra muscular injection in child health center in Haryana. A Total of 212 children aged 4-6 yrs participated in the study. The first group was given injection in a conventional way that is without manual pressure being applied prior to the injection. The second group was given injection with manual pressure being applied prior to the injection for each sample. The samples with manual pressure applied before injections reported Lower pain (M±SD=1.32±0.77) intensity scores, while those without the application of manual pressure before injections reported higher pain intensity scores (M±SD=6.7±2.6). Study finding shows

that applying manual pressure to an injection site before performing an injection could be an effective means of decreasing pain intensity**. (Mitchel J. R & Whitney F. W,2014)**

A study of 105 children aged 4 to 6 years undergoing immunization with diphtheria-tetanus pertussis (DTP) were randomized to one of three treatments: light stroking of the skin near the injection site, bubble blowing by the child, or standard care. Pain was measured with the 10point self-report oucher scale. No statistical difference was found between light stroking and bubble blowing, although numerically less pain was reported in the light stroking group (1.89versus 2.00). Both treatments together resulted in less pain than the control group (2.89,p = 0.013).The study findings depicts that distraction makes the child to be engaged, the group receiving light touch many have been at an advantage because the intervention did not require the child to attend to the activity. **(Sparks L, 2014)**

A randomized control trial was done to evaluate the effectiveness of topical eutectic mixture of local anesthetic (EMLA) cream in reducing the pain associated with vaccination injections. Eligible children were randomly assigned to receive either EMLA or placebo cream. The Modified Behavioral Pain Scale (MBPS) was used to assess baseline and post vaccination pain scores, while a visual analogue scale (VAS) was used to assess pain at the time of the needle prick and at the end of the injection. A total of 107 children were enrolled in the EMLA group and 109 children in the placebo group. The difference between the pre- and post vaccination MBPS scores was significantly lower in the EMLA group than in the placebo group (2.56-1.96 versus 3.95-2.20). The VAS scores at the time of the needle prick and after the injection were significantly lower in the EMLA group compared with the placebo group (1.60-1.67 versus 3.24-2.01; 3.29-2.27 versus 4.86-2.20).The study results shows that application of EMLA-cream can be effectively incorporated as a routine pain relieving intervention during routine vaccination. **(Manal Abuelkheir, 2014).**

A randomized clinical trial was conducted among ninety-six infants. Sample were allocated randomly to three groups (breast feeding, massage, and control groups). The study population comprised all infants, accompanied by their mothers to health centers in Isfahan for vaccination of hepatitis B and DPT at 6 months of age and for MMR at 12 months of age. Data was gathered using questionnaire and checklist [neonatal infant pain scale (NIPS)]. Findings of

the study showed that the three groups had no statistically significant difference in terms of demographic characteristics like age, gender, weight ($P > 0.05$). The mean pain scores in the breast feeding group, massage therapy, and control group were 3.4, 3.9, and 4.8 ($P < 0.05$). Differences between the group, massage therapy and breast feeding ($P = 0.041$), breast feeding group and control ($P = 0.001$), and massage therapy and control groups ($P = 0.002$) were statistically significant. The results of the study denotes that breast feeding during vaccination has more analgesic effect than massage therapy. **(Mitra Savabi Esfahani, 2014)**

An experimental, one group pre-test and post test study was conducted in J. J.Hospital Mumbai to evaluate the effectiveness of manual pressure application & muscle relaxation therapy on intramuscular injection. Fifty patients in age group of 15 - 55 years who receive IM injection benzathine penicillin in cardiology OPD were selected by non-probability convenient sampling technique. The study finding shows that manual pressure effective in management of pain. In pre test most 39(78%) subjects had moderate response followed by 11(22%) subjects with severe response none of the subjects were in no and mild response. The post intervention score revealed that most 47(94%) subjects were in mild response. (**Gitanjali Zore, Ragina Dias, 2014)**

A randomized control trial was performed to determine the effect of application of Manual pressure over the injection site on pain. There were 74 participants between 18 to 20 years of age who were participating in an immunization vaccination campaign. The left and right arms of the participants were randomized to receive an intramuscular injection of hepatitis B vaccine with and without the application of pressure at the injection site. A mechanical pressure detection device was placed between the participant's arm and the investigator's thumb. Manual pressure was applied in a standardized way to the deltoid region of the participant's arm for 10 seconds prior to the delivery of vaccination. Pain intensity measured by the 10 point pain intensity verbal rating scale. The mean pain score was lower ($M \pm SD = 2.3 \pm 0.90$) among patients who received manual pressure prior to injection. The mean score higher for perceived pain intensity for both control conditions ($M \pm SD = 6.1 \pm 2.1, p < 0.001$). The mean pressure recorded by the detection device was 190.82 mm Hg (SD=5.25). The study results revealed that applied pressure at the intramuscular site reduced the amount of perceived pain ($t = 6.7, p < 0.001$). **(Chung JW, Ng WM, Wong TK, 2013)**

2.3. Reviews related to Effectiveness of Helfer skin tap technique in reducing pain perception of clients undergoing intramuscular injection

A randomized controlled trail was conducted in JIPMER, Pudhucherry to assess the effectiveness of Helfer skin tap technique on pain reduction among the patients receiving intramuscular injection. The patients who were getting analgesics and intramuscular injection in OPD, casualty and trauma ward and both men and women between the age group of 21-60 years were selected as sample. Purposive sampling technique used to select the patient and simple random sampling technique used to allocate 67 patients each in experimental group and control group. The level of pain was measured by using Numerical Pain Rating Scale. The study findings revealed that there was a effective pain reduction among patient who received Helfer skin tap technique than the routine group (M±SD= 0.67±1.17 at $p<0.001$). **(Vathani G, Kumari. M. J, 2017)**

A True experimental study was conducted at tertiary care hospital in Lucknow among 100 newborn babies. Purposive Sampling technique was used to select the eligible population and simple random is used to allocate the subject into experimental and control group. Neonatal Infant Pain scale (NIPS) was used to assess the pain level of newborn. The collected data was analyzed using a descriptive and inferential statistics. A study finding high light that 86% of neonates in the experimental had mild pain, only 14% perceived moderate pain during the IM injection by using Helfer skin tap technique. Neonates in the control group (86%) had severe pain, only 14% perceived moderate pain during IM injection by using routine technique. There is a significance decrease in pain score between the administration of IM injection with Helfer skin tap technique ($z=4.003$ at $P<0.05$).This study explored the effect of Helfer skin tap technique over the skin before and during IM injection for pain reduction. **(Maj Sivapriya, Col Leena Kumari, 2015)**

A study was conducted to assess the effectiveness of Helfer skin tap technique and routine technique on pain reduction among children receiving intramuscular injection at Government General Hospital, Puducherry by simple random sampling technique (lottery method), 25 infants were first assigned for intramuscular injection using Helfer Skin Tap Technique and other 25 Infants were first assigned for intramuscular injection using Routine Technique. The subjects were examined with 4 variables are pain, systolic and diastolic blood

pressure and pulse rate. It was indicated that the perception of pain intensity is less when intra muscular injection is administered using Helfer Skin Tap Technique ($t=4.9$, $p<0.05$)**. (Maria Therese1, Suriya Devi, 2015)**

A quasi experimental study was conducted in Canada to determine the effectiveness of physical intervention in reducing pain during intramuscular injection among 66 children (6-18 yrs age) participated in this study. The method used was tapping the skin close to the injection site before and during the injection. The result revealed that there is a significant reduction of pain before ($M\pm SD=2.5\pm0.7$) and during vaccine administration ($M\pm SD=1.5\pm0.53$, $P=0.03$). The findings of the study suggest that the relaxation of muscle will help in reducing the injection pain ($t=4.2$, $p<0.01$)**. (Toddio A, et al., 2014).**

A true experimental study was conducted in Manipal college of nursing, to determine the skin tap technique in pain reduction during the DPT vaccination. A post test only control group design was adopted for the study. Purposive sampling technique was used to select the sample. random allocation of treatment using chit method non replacement technique. The sample size was sixty; thirty each in experimental and control group. The study revealed that 24(80%) infant had mild pain response in experimental group whereas only 84% of the control group experienced in moderate and severe pain. There was a significant difference ($t=7.14$ at $p<0.001$) in level of pain between experimental & control group. **(Jose, Rose Mary, 2013)**

A quasi experimental study was conducted in St. John's medical college ,Bangalore to determine the effectiveness of Helfer skin tap technique on pain during intramuscular injection among adult patient(18-30yrs). Sixty subjects received four injections in which two injections with standard technique and two injections with Helfer skin tap technique .Pain assessment was done by 6-10 numerical intensity pain scale. The mean pain score using Helfer skin tap technique.($M\pm SD=15\pm1.1$)was less than the pain scored by standard technique ($M\pm SD=2.9\pm1.9$). The pain level was significantly reduced in treatment group($p<0.001$)**.(George J.A, 2012)**

A Meta analysis was done to evaluate the effectiveness of physical and procedural interventions for reducing pain and related outcomes during vaccination. A total of 31 studies were analysed. This study result concluded that acute infant distress was diminished during intramuscular injection without aspiration (n=313). Injecting the most painful vaccine last during vaccinations reduced acute infant distress (n=196). Simultaneous injections reduced acute infant

distress compared with sequential injections (n=172).Less infant distress during the acute and recovery phases combined occurred with vastus lateralis vs deltoid injections (n=185). Skin-to-skin contact in neonates (n=736) reduced acute distress. Skin tapping near the injection site before and during vaccination reduced the infants acute distress (n=107). Holding after vaccination (n=417) reduced infant distress during the acute and recovery phases combined. Self-reported fear was reduced for children positioned upright (n=107). Non-nutritive sucking (n=186) reduced acute distress in infants.(**HapperinS.A,Mc Grath p,2012)**

A Quasi experimental study was conducted to assess the effect of Helfer rhythmic skin tap technique on procedural pain among patients receiving intramuscular injection at orthopedic wards in Govt. Medical College Kozhikode, Kerala .A total of of 82 patients were selected the age group between 20-30 years, who were receiving Inj. voveran . Simple random sampling technique was used to allocate the patient in intervention and routine group. The patient pain level was measured by using Numerical Pain Intensity Scale and Visual Analogue scale. Data were analysed by SPSS. The study result reveals that there was a significant reduction in pain perception of patients receiving IM injection with Helfer Rhythmic skin tap technique($t=25.5, p<0.001$).There was no association between pain perception of patient receiving IM injection with Helfer Rhythmic skin tap technique and selected socio demographic variables like age, gender, weight**,** religion, educational status. **(Saleena Shah, Asha Narayanan, 2012)**

Summary:

Literatures related to pain experience of children undergoing immunization, management of intramuscular vaccination pain, Helfer skin tap technique on intramuscular vaccination pain help to identify the measures to reduce the intramuscular vaccination pain among infants. Most of the literature supported the present study. Literature studies included descriptive, randomized, experimental, observational study which were reviewed deeply for the present study. This extensive review has helped the researcher to have a deep insight into the problem under the study and has guided the researcher in the development of research instruments, data collection procedure &plan for data analysis.

CHAPTER –III

MATERIALS AND METHODS

Research design is a blue print for conducting a study. Designing a research involves development of a plan strategy that will guide the collection and analysis of the data. The methodology of the study constitutes the research design, tool, and procedure for data collection and techniques for data collection, report of pilot study. **(Suresh K Sharma., 2007).** The present study was done to determine the effectiveness of Helfer skin tap technique on reduction of pain among infants under going intramuscular vaccination in Tertiary care settings, Coimbatore. The methodology of the study constitutes of research design, setting, selection of population and sampling criteria for selecting samples, instruments and tools for data collection and methods of data analysis.

3.1 Research approach:

Research approach refers to the way in which the researcher plans or structures the research process. It is a set of the flexible spots designed to keep the research in the right direction. This scientific process helps to acquire dependable and useful information. In this study, quantitative research approach was adopted.

Research design:

Quasi- experimental design:

Quasi experiments are like true experiment, it involve an intervention. However, quasi experimental design lack randomization (the signature of a true experiment). **(Polit., 2009).**

Time series design:

The research design is the structural framework for the study implementation. In order to ensure validity of the study. In a time series design, the researcher periodically observe or measure the subject. (**Suresh .K.Sharma., 2011).**

Time series research design was adopted for the present study. The pre assessment of infants was made at 5minutes prior to the administration of intramuscular vaccine in treatment and routine group. Helfer skin tap technique was given only to the infants of treatment group.

During Intramuscular vaccination the pain assessment was made in both the groups and Post test level of pain were also assessed at 1st minute, 5th minute, and at10th minute in routine and treatment group by using FLACC pain scale.

Research design:

Quasi experimental design:

Time series design:

Treatment group

$O_1 \longrightarrow X_1 \longrightarrow O_2 \longrightarrow O_3 \longrightarrow O_4 \longrightarrow O_5$

Routine group

$O_1 \longrightarrow X \longrightarrow O_2 \longrightarrow O_3 \longrightarrow O_4 \longrightarrow O_5$

O_1- Pre assessment of infants before 5minutes who underwent intramuscular vaccination by using FLACC pain scale.

X_1 –Administration of Helfer skin tap technique.

X- Routine care.

O_2- Post assessment of infants pain during intramuscular vaccination.

O_3- Post assessment of infants pain after the 1st minute

O_4- Post assessment of infants pain after the 5th minute

O_5 - Post assessment of infants pain after the 10th minute

3.2 Variables of the Study

3.2.1 Independent variable:

- The independent variables within the study were Helfer skin tap technique administered to infants undergoing intramuscular vaccination.

3.2.2 Dependent variable:

- The dependent variable in the study was level of intramuscular vaccination pain in infants.
- Type of vaccination among infants undergoing intramuscular vaccination.

3.3 Setting of the study:

This study was conducted in pediatric vaccination clinic at PSG Hospitals, Peelamedu, Coimbatore. A multi specialty hospital and research centre with bed strength of 1315 which caters multi lingual patients from various parts of the country. The hospital is reputed as the first teaching hospital in Tamilnadu and the third teaching hospital in India to get certified by National Accredited Board for Hospitals and Health Care Providers (NABH). Approximately 6238 children are immunized and 1631 infants receive penta and easy six vaccine, annually in pediatric vaccination clinic. There are two nurses giving the vaccination for children in pediatric vaccination clinic.

3.4 Population and sampling:

The population consists of infants (6-4wks) undergoing intramuscular vaccination at PSG Hospitals, Coimbatore. The total numbers of infants undergoing penta and easy six vaccination from 2016 to 2017 were 1631.

3.4.1 Sampling technique and sample size:

The purposive sampling technique was used to select the samples for the present study. Sixty Infants those who met the inclusion criteria of receiving Penta and Easy six vaccines were included as sample. Out of 60 infants, 30 were allocated to intervention group who received the Helfer skin tap technique and 30 in the routine group who received routine care by using simple random technique.

Sample size and calculation:

The sample size was calculated by using Power analysis method.

Power analysis method

$$n = \frac{Z^2 \times N \times SD^2p}{(N-1)\, e^2 + Z^2 \times SD^2p}$$

N= size of population

n = size of sample

e = acceptable error

SDp = standard deviation of a population

Z = standard variation at a given confidence level

$$n = \frac{(1.96)^2 \times 1631 \times (9.4)^2}{(1631 - 1) \times (2.5)^2 + (1.96)^2 \times (9.4)^2}$$

$$= \frac{553402.21}{10934.3}$$

n = 59

The sample size calculated for the present study was 60 infants receiving penta and easy six vaccine. Thirty in both group.

3.4.2 Sampling Criteria:

3.4.2.1 Inclusion criteria:

- Infants with the age group of 6-14 weeks
- Infants receiving penta vaccine((Diphtheria, Pertussis, Tetanus, Hepatitis, Haemophilus influenza)
- Infants receiving easy six vaccine (Diphtheria, Pertussis, Tetanus, Hepatitis, Haemophilus influenza, inactivated polio vaccine)

3.4.2.2 Exclusion criteria

- Infants of mother who are not willing to give consent to participate in the study.

3.5 Instrument and tool for data collection:

Collection of appropriate information which provides necessary data for the study is an important aspect of any research. A thorough literature review undertaken to decide on the tools to be used for data collection based on the objectives of the study

The tool for the study consists of two section**;**

Section –A: Demographic variable.

Section-B: Pain assessment by using FLACC pain scale

Section –A: Demographic variable.

The demographic variables that includes infants age, gender, weight, gestational age at birth, Name of the vaccine, Frequency of vaccine.(Annexure-IV.A)

Section-B: FLACC pain scale. **(**Annexure-IV.B)

- The FLACC Scale was Developed by Sandra Merkel, Voepol-Lewis T.et al.,(1997)
- It consists of characteristics like Face, leg, Activity, Cry, Consolability which is measured to assess pain level for infants between the ages of 6-14wks.
- Each criteria assigned a score of 0,1or 2.
- The FLACC pain scale has marking from 0 to 10, where 0 indicate relaxed and comfortable and 10 indicate severe pain. The interpretation of FLACC pain rating scale has the score of 0(relaxed and comfortable), 1-3(mild pain), 4-6(moderate pain), 7-10(severe pain).
- FLACC scale has an established inter rater reliability value of 0.88 (Spearman's coefficient correlation).

3.5.1 Validity and reliability of tool:

Validity of the tool:

Content Validity of the tool was obtained from nursing and medical experts of different departments along with objective of the study. The experts gave their opinions, clarity and appropriateness for the tool.

Reliability of the tool:

Reliability of the tool FLACC scale was determined by using inter rater reliability method. It was computed using spearman rank coefficient method. The reliability of the FLACC scale was found to be 0.94 .The tool was found to be highly reliable for the study.

3.5.2 Techniques of Data collection:

Demographic data were collected through interview method and retrieved from vaccination card. Intramuscular vaccination pain among infants were assessed using FLACC pain scale through observation method.

Intervention:

Helfer skin tap technique: Tapping over the intramuscular injection site with the palmer aspect of finger 16 times before and the 3 counts during the intramuscular vaccination and continue the tapping till needle was removed

Step:

- Infants were identified as per inclusion criteria
- Infants were placed in supine position
- 5 minutes prior to intervention, the infants were assessed by using FLACC pain scale.
- After identification of the intramuscular vaccination site, the vaccination site was tapped 16 times approximately 10 seconds before intramuscular vaccination with the palmer aspect of the dominant hand to relax the muscle.
- During the vaccination the researcher tapped near the vaccination site 3 times, when the vaccination given by nurses.

- Continued tapping near the vaccination site till the needle was removed.
- Assess the pain level during intramuscular vaccination using full video.
- After the vaccination the pain level is assessed at 1^{st} minute, 5^{th} minute and 10^{th} minute using FLACC scale.

3.5.3 Data collection procedure

Formal written permission was sought from the administrator an HOD of the paediatric medical department, PSG Hospital, Peelamedu, Coimbatore. The approval for conducting the study was received from IHEC of the institution. The data collection procedure was carried out from 02-2-2018 to 28-2-2018.

Data collection procedure steps:

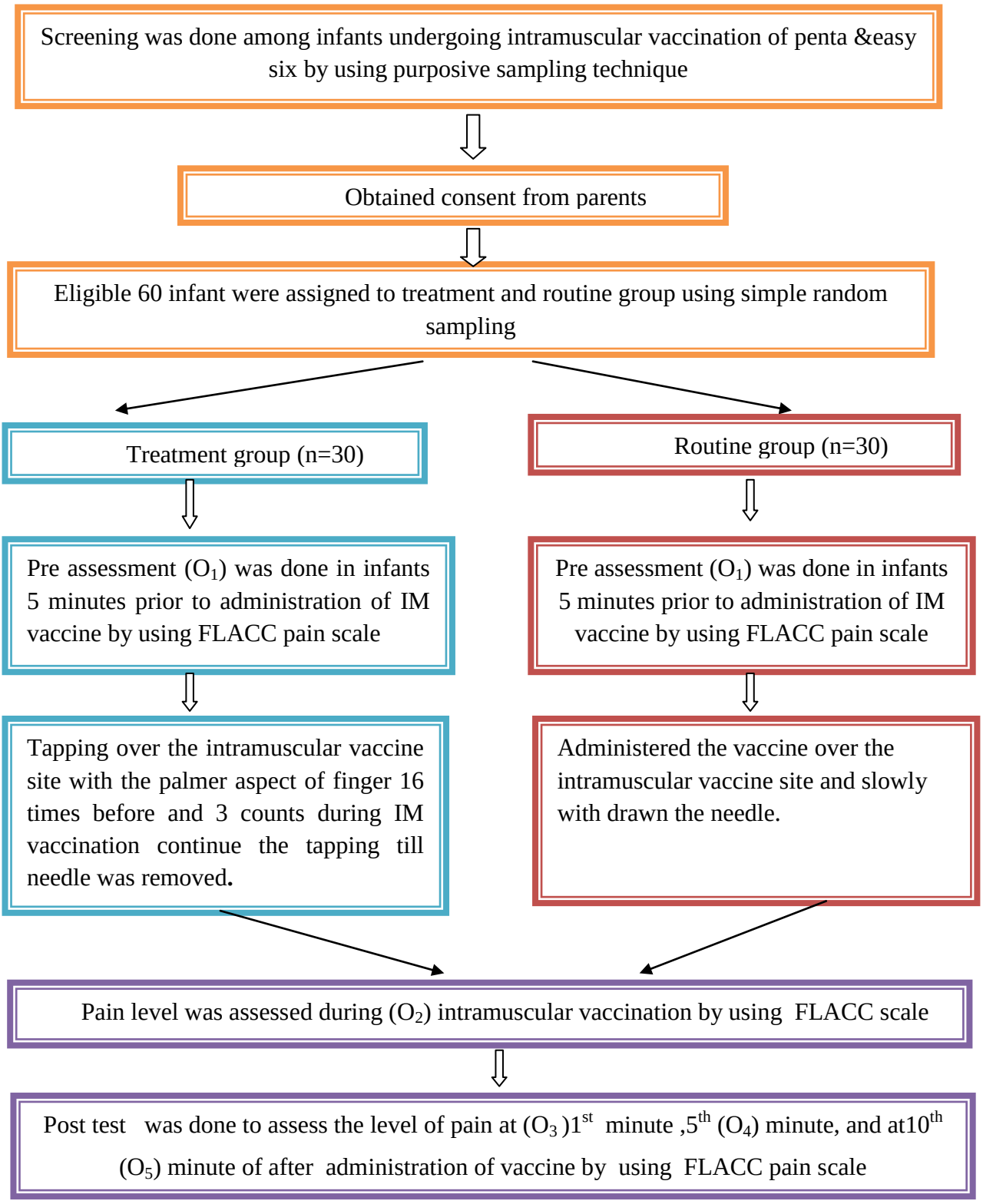

Figure 3.1 Schematic representation of data collection procedure

3.6 Ethical approval:

The Institutional Human Ethics Committee, PSG Institute of Medical Science and Research submitted the proposal and approved (Annexure II) the study to conduct. The Institutional Human Ethics Committee consists of fifteen members of different areas of expertise. After getting clearance from Institutional Human Ethics Committee data collection was done.

3.7 Report of the pilot study:

Pilot study was conducted to test the practicability and feasibility of the tool for conducting the main study. It was conducted for a period of one week from 30.10.2017 to 05-11-17, in the vaccination clinic, PSG hospitals, Peelamedu, Coimbatore. For pilot study, 10 infants were selected those who are underwent penta &easy six vaccination by using purposive sampling technique according to the inclusion criteria. Among 10 infants, 5 in treatment group and 5 in routine group which was assigned by simple random sampling technique. Pre assessment was done 5 minutes prior to administration of intramuscular vaccine in routine and treatment group. Administered the Helfer skin tap technique only to the treatment group. During Intramuscular vaccination, the pain assessment was done in both the groups and post test level of pain was assessed in intervention and routine group at 1^{st} minute,5^{th} minute, and at 10^{th} minute after the intramuscular vaccination by using FLACC pain scale . At the end of the pilot study, Helfer Skin tap technique was effective to reduce the intramuscular vaccination pain. Through the pilot study inter rater reliability (r=0.94) and practicability of the tool and feasibility of the study has been found.

3.7.1 Changes Brought After Pilot Study;

Changes incorporated after the pilot study was to assess the level of pain in infants before administration of vaccine and to find out the difference between pretest and post test pain values among intervention &routine group.

3.8 Data analysis plan:

The data was analyzed using descriptive and inferential statistics

Descriptive statistics:

- Frequency and percentage distribution will be used for describing demographic variables and level of pain before, during & after the vaccination among infants undergoing intramuscular vaccination.
- Mean and standard deviation will be used to describe the pain level of infants before, during & after the vaccination among infants undergoing intramuscular vaccination.

Inferential statistics:

- Paired 't' test will be used to find the significant differences between the pre-test and post-test level of pain during intramuscular vaccination among infants in treatment and routine group.
- Independent 't' test will be used to assess the significant differences in during and post-test score at various time intervals between the treatment and routine group.
- Chi square test will be used to find out the association of pain level of infants during intramuscular vaccination with the selected demographic variables.

Summary:

This chapter discussed the material and methodology used for the present study. The methods used in this study are quasi experimental, time series design and purposive sampling technique .This chapter also dealt with the research design, variable, settings, sample selection criteria, instrument and tools for data collection and data analysis plan. Next chapter will be dealt on data analysis and interpretation.

CHAPTER-IV

DATA ANALYSIS AND INTERPRETATION

Analysis is a process of organizing the data in such a way that research question can be answered **(Polit and Hungler, 2009)**. This chapter deals with the analysis of the data collected from the parents and the interpretation of the results helps in making sense of the results of a study. The data was collected to assess the effectiveness of Helfer skin tap technique on pain reduction among infants undergoing intramuscular vaccination in tertiary care setting, Coimbatore.

The analysis in this chapter includes:

4.1 Frequency and percentage distribution of infants undergoing intramuscular vaccination in treatment and routine group according to demographic variables.

4.2. Frequency and percentage distribution of various degree of pre and post test FLACC pain score between treatment and routine group.

4.3. Comparison of pre and post test level of intramuscular vaccination pain among infants undergoing intramuscular vaccination in treatment group by using paired‘t’ test.

4.4 Comparison of pre and post test level of intramuscular vaccination pain among infants undergoing intramuscular vaccination pain in routine group by using paired‘t’ test.

4.5 Comparison pain score at various time intervals of intramuscular vaccination pain between treatment and routine group of infants undergoing intramuscular vaccination by using independent ‘t’ test.

4.6 Association of selected demographic variable with pain level of infant during IM vaccination in treatment group and routine group.

Table 4.1 Frequency and percentage distribution of infants undergoing intramuscular vaccination in treatment and routine group according to demographic variables

n=60

Demographic Variable	Treatment group n=30				Routine group n=30			
Age and Gender (Age in Years)	**Male**	**%**	**Female**	**%**	**Male**	**%**	**Female**	**%**
6 weeks	2	6.67%	1	3.33%	5	16.66%	2	6.67%
10 weeks	7	23.33%	7	23.33%	4	13.33%	9	30%
14 weeks	8	26.67%	5	16.67%	5	16.66%	5	16.67%
Gestational age at birth								
35-36wks	1	3.33%	1	3.33%	2	6.67%	1	3.33%
37-38wks	8	26.66%	11	36.67%	9	30%	7	23.33%
39-40wks	8	26.67%	1	3.33%	3	10%	8	26.66%
Weight of the baby								
3.6-4.5kg	3	10%	2	6.67%	6	20%	3	10%
4.6-5.5kg	9	30%	11	36.67%	3	10%	9	26.67%
5.6-6.5kg	5	16.67%	-	-	5	16.66%	4	13.33%
Name of the vaccine								
Easy six	15	50%	8	34.78%	6	20%	14	46.67%
Penta vac	2	6.67%	5	16.66%	8	26.67%	2	6.67%
Dosage of vaccination								
I-Dose	2	6.67%	1	3.33%	5	16.66%	2	6.67%
II-Dose	7	23. 33%	7	23.33%	4	13.33%	9	30%
III- Dose	8	23.33%	5	16.67%	5	16.66%	5	16.66%

Table 4.1 shows that out of 60 Infants, Majority of the Infants 50 (83%) were in age group of 10-14wks in treatment group and routine group and about half of the Infants 31(51.67%) were male this comprised of 17(28.33%) Infants in treatment group and 14 (23.34%) infants in routine group. More than half of the Infants 35 (58.34%) were under the 37-38 weeks of gestational age at birth this comprised of 19 (31.67%) Infants in treatment group and 16 (26.67%) infants in routine group. More than half of the of the Infants 32 (53.33%) were weighing between (4.6-5.5kg) this comprised of 20(33.33%) Infants in treatment group and 12(20%) routine group. Majority of the Infants 43 (71.67%) had easy six vaccines this comprised 23 (38.33%) Infants in treatment group and 20 (38.33%) in routine group and 27 (45%) of infants had IInd dose of vaccine this comprised of 14 (23.33%) Infants in treatment group and 13(21.67%) in routine group.

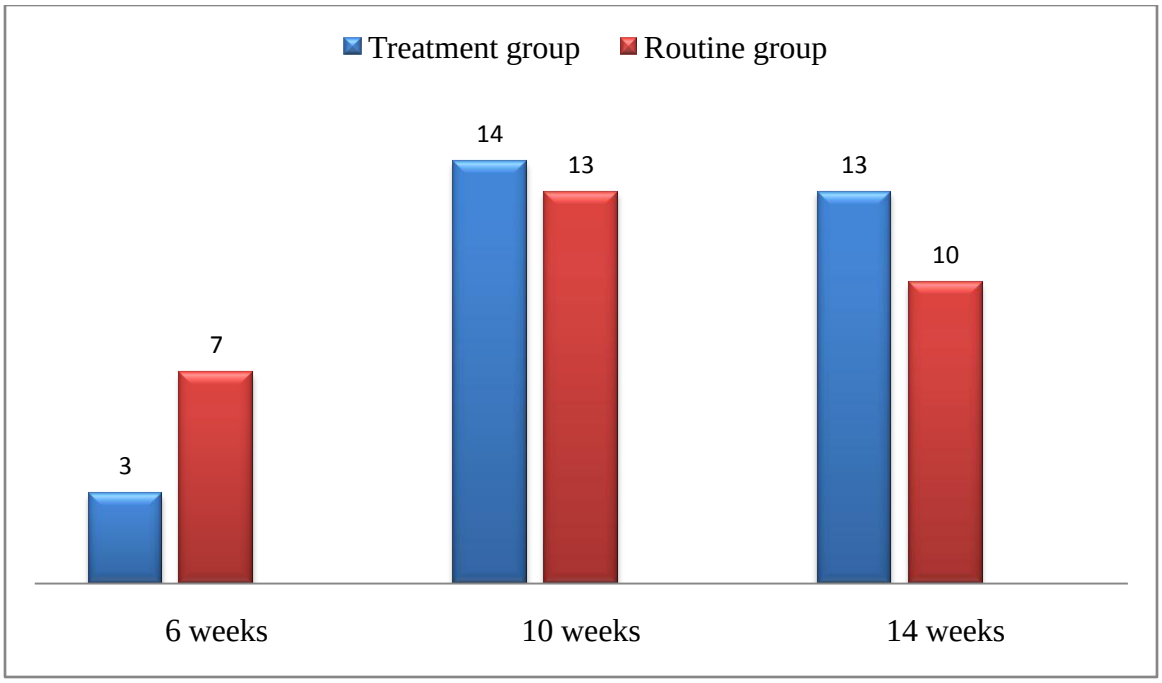

Figure 4.1.1: column diagram shows the frequency distribution of infants undergoing intramuscular vaccination in treatment and routine group according to their age

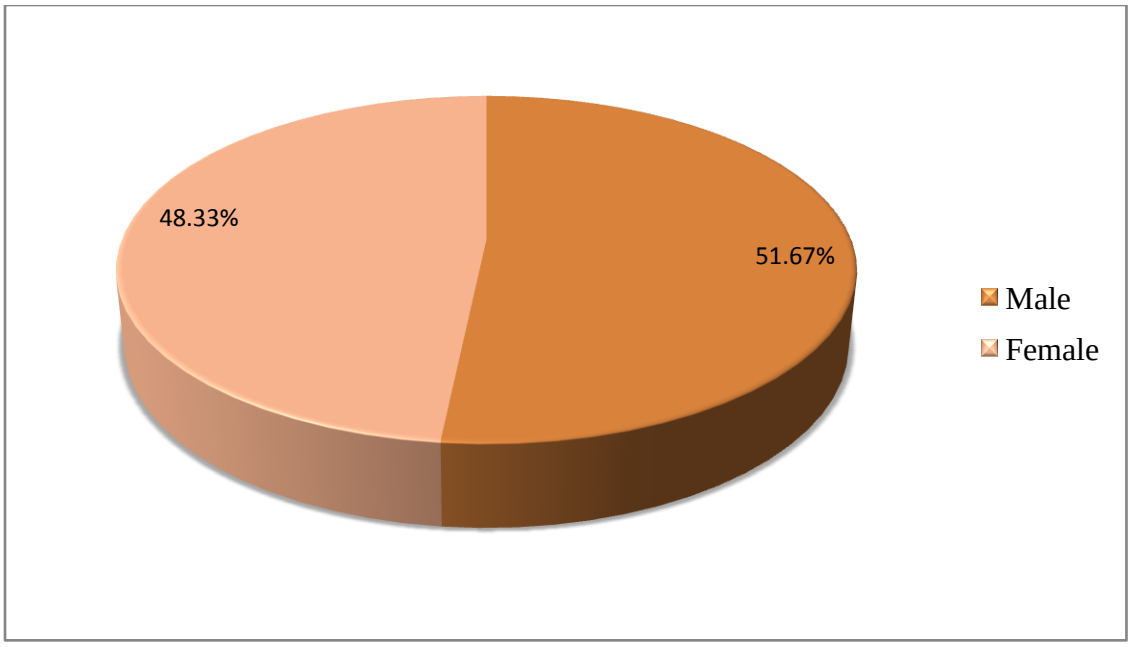

Figure 4.1.2: Pie diagram shows the percentage distribution of infants undergoing intramuscular vaccination in treatment and routine group according to their gender

Table 4.2 Frequency and percentage distribution of various degree of pre and post test FLACC pain score between treatment and routine group n=60

S. No	FLACC Pain scale	Level of pain	Treatment group n = 30										Routine group n= 30									
			pretest (Before 5minutes)		During		Post test(after)						pretest (Before 5minutes)		During		Post test(after)					
							1st minute		5th minute		10th minute						1st minute		5th minute		10th minute	
			F	%	f	%	f	%	f	%	f	%	f	%	f	%	F	%	f	%	f	%
1	0	Relaxed and comfortable	27	90	1	3.33	1	3.33	10	33.33	26	86.67	23	76.67	-	-	-	-	-	-	6	20
2	1 – 3	Mild pain	-	-	6	20	11	36.67	15	50	4	13.33	4	13.33	-	-	-	-	16	53.33	24	80
3	4 – 7	Moderate pain	2	6.67	19	63.33	18	60	5	16.67	-	-	2	6.67	3	10	18	60	14	46.67	-	-
4	8 – 10	Severe pain	1	3.33	4	13.33	-	-	-		-	-	1	3.33	27	90	12	40	-	-	-	-

Table 4.2 shows that during pre assessment in treatment group 27(90%) infants were relaxed and comfortable where as in routine group23 (76.77%) infants were relaxed and comfortable. During vaccination in treatment group 19(63.33%) infants experienced moderate pain where as in routine group most of the infants 27(90%) experienced severe pain, only 3(10%) infants experienced moderate pain. On post assessment at 1st minute in treatment group 18(60%) infants had moderate pain where as in routine group 12(40%) infants had severe pain. Five minutes after the vaccination in treatment group 15(50%) infants had mild pain, 10(33.33%) infants relaxed and comfortable where as in routine group 16(53.33%) infants had mild pain&14(46.67%) infants had moderate pain. Ten minutes after the vaccination 26(86.6%) infants were relaxed and comfortable where as in routine group 6(20%)infants were relaxed and comfortable and 24(80%) infants experienced mild pain.

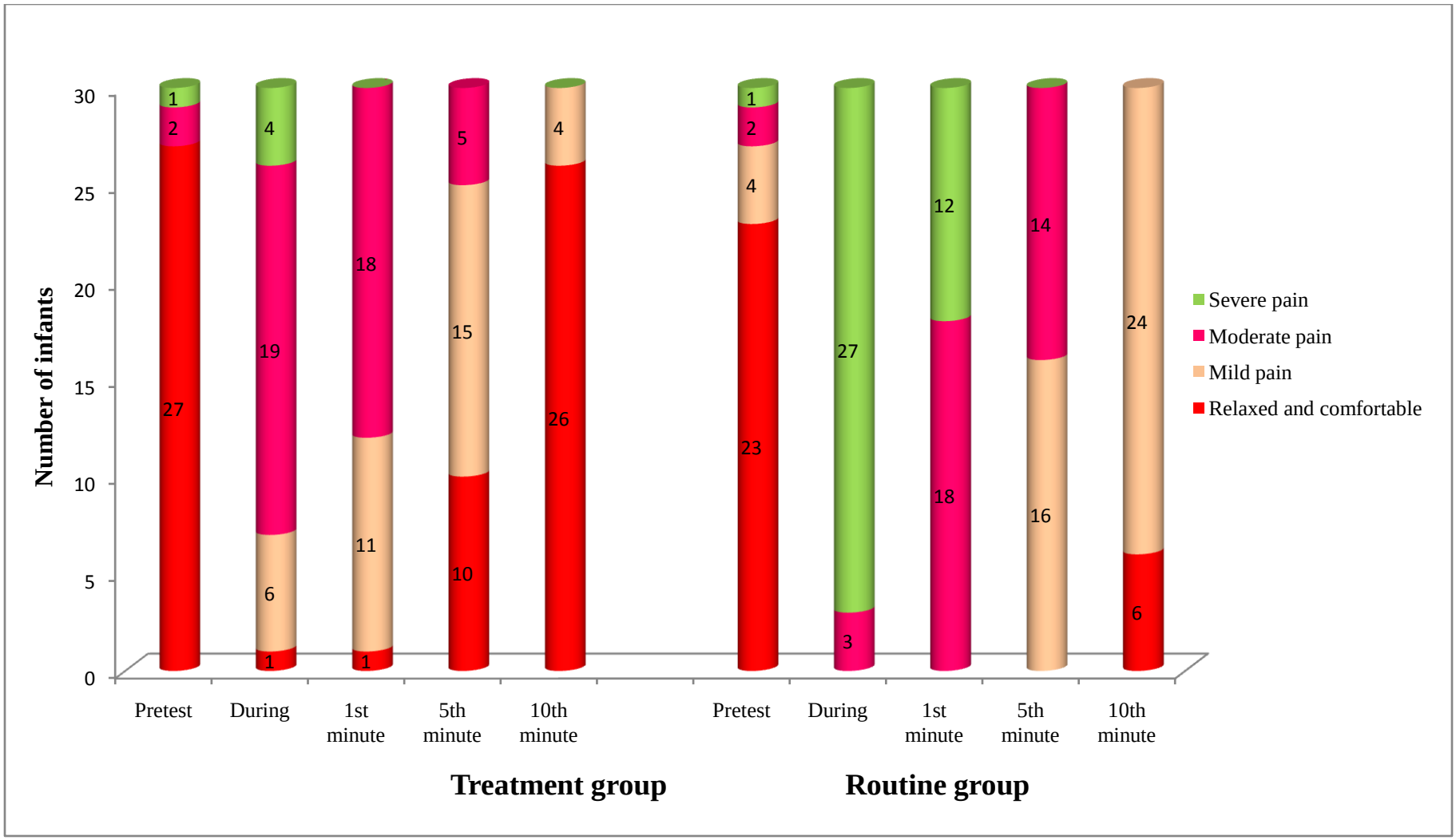

Figure 4.2Multiple stacked bar diagram shows the frequency distribution of various degree of pre and post test FLACC pain score between treatment and routine group

Table 4.3: Comparison of pre and post test level of intramuscular vaccination pain among infants undergoing intramuscular vaccination pain in treatment group by using paired 't' test

H_{01}: there will not be a significant difference in the pretest and post test level of pain during intramuscular vaccination among infants in treatment group. **n=30**

S.No	Treatment group	Mean ± SD	Calculated 't' value	Table Value	P value
1	Pre test	0.60±1.89	10.32	3.64	0.001***
2	During	5.30±1.74			
3	1st minute	3.93±1.51	7.756	3.64	0.001***
4	5th minute	2.03±1.69	3.139	3.64	0.001***
5	10th minute	0.30±0.79	0.835	0.85	0.425

(Range of pain: 0-Relaxed and comfortable, 1-3-Mild pain, 4-6-moderate pain, 7-10-severe pain)

Note: Statistically significant ***p<0.001

Table 4.3 describes that during pretest infants were relaxed and comfortable (M±SD=0.60±1.89), during vaccination infants experienced moderate pain(M ± SD=5.30±1.74) and post test at 1st minute infants had mild pain(M ± SD=3.93±1.51), 5th minutes infants experienced mild pain(M ± SD=2.03±1.69) and at10th minutes infants were relaxed and comfortable (M ± SD=0.30±0.79). It shows that there was a significant reduction of pain score during vaccination (t=10.32 at p<0.001) and after the vaccination at 1st minute (t=7.756 at p<0.001), 5th minute (t=3.139 at p<0.001). Thus null hypothesis is rejected and research hypothesis is accepted. Hence there was a significant reduction in pain perception among infants undergoing intramuscular vaccination with Helfer skin tap technique.

Table 4.4 Comparison of pre and post test level of pain among infants undergoing intramuscular vaccination pain in routine group by using paired 't' test

H_{01}: there will not be a significant difference in the pretest and post test level of pain during intramuscular vaccination among infants in routine group **n=30**

S.No	Routine group	Mean ±SD	Calculated 't' value	Table value	P value
1	Pre test	0.93±1.89			
2	During	8.70±0.2	20.79	3.64	0.001***
3	1st minute	6.43±1.04	16.10	3.64	0.001***
4	5th minute	4.03± 1.33	9.02	3.64	0.001***
5	10th minute	1.87±1.17	2.21	1.69	0.05*

(Range of pain :0-Relaxed and comfortable,1-3-Mild pain, 4-6-moderate pain, 7-10-severe pain)

Note: - Statistically significant *p<0.05, ***p<0.001

Table 4.4 describes that in routine group during pretest infants were relaxed and comfortable (M± SD=0.60±1.89),during vaccination infants experienced severe pain(M ± SD=8.70±0.2,) and post test at 1st minute infants had moderate pain(M ± SD=6.43±1.04), 5th minutes infants remains in moderate pain (M ± SD= 4.03± 1.33) and at10th minutes infants experienced mild pain (M ± SD=1.87±1.17). It shows that there was a significant difference in the pain perception during vaccination (t=20.79 at p<0.05), after the vaccination at 1st minute (t=16.10 at p<0.001), 5th minute (t=9.02 at p<0.001) and at 10th minute (t=2.21 at p<0.05). Hence null hypothesis is rejected and research hypothesis is accepted.

Table 4.5: Comparison of pain score at various time intervals of intramuscular vaccination pain between treatment and routine group of infants undergoing intramuscular vaccination by using independent 't' test

H_{02}: there will not be a significant difference in pain score at various time intervals between routine and treatment group **n=60**

Post test	Treatment group	Routine group	Calculated 't' value	Table value	P value
	Mean ± SD	Mean ± SD			
During	5.30 ± 1.74	8.70 ± 1.02	9.20	3.46	0.001***
1st minute	3.93 ± 1.51	6.83 ± 1.04	8.30	3.46	0.001***
5th minute	2.03 ± 1.69	4.03 ± 1.33	5.09	3.46	0.001***
10 th minute	0.30 ± 0.79	1.87 ± 1.17	6.07	3.46	0.001***
Over all Mean and SD	2.89 ± 2.18	5.42 ± 2.93	3.79	3.46	0.001***

(Range of pain :0-Relaxed and comfortable,1-3-Mild pain, 4-6-moderate pain, 7-10-severe pain)

Note: - Statistically significant ***P<0.001

Table 4.5 Indicate that there was a significant difference in the pain level of infants in the treatment group and routine group (over all M± SD=2.89 ± 2.18, 5.42 ± 2.93,t= 3.79). During the intramuscular vaccination in treatment group infants experienced moderate pain (5.30 ± 1.74) where as in routine group experienced (8.70 ± 1.02) severe pain. Post test level of pain at 1st minute the treatment group infants had mild pain (3.93 ± 1.51)where as in routine group infants had moderate pain (6.83 ± 1.04), at 5th minute in treatment group infants experienced mild pain(2.03 ± 1.69) where as in routine group infants experienced moderate pain (4.03 ± 1.33) at 10th minute in treatment group infants were relaxed and comfortable(0.30 ± 0.79) where as in routine group infants experienced mild pain(1.87 ± 1.17). Hence null hypothesis is rejected and research hypothesis is accepted. It can be concluded that Helfer skin tap technique was effective in reducing the pain perception in treatment group compared to routine group during and after intramuscular vaccination.

Table 4.6 Association of selected demographic variable with pain level of infants during intramuscular vaccination in treatment group

H_{03}: There will not be a significant association between the pain level of infants and selected demographic variables during intra muscular vaccination **n=30**

Demographic Variables	Treatment group								df	Calculated $\chi 2$ value	P value	Table Value
	Relaxed		Mild		Moderate		Severe					
	F	%	F	%	%		F	%				
AGE												
6 weeks	-	-	1	3.33	2	6.67	-	-	6	6.87 NS	0.33	12.59
10weeks	-	-	4	13.33	7	23.33	4	13.33				
14weeks	1	3.33	1	3.33	10	33.33	-	-				
GENDER												
Male	1	3.33	4	13.33	9	30	3	10	3	2.18 NS	0.53	7.81
Female	-	-	2	6.67	10	33.33	1	3.33				
GESTATIONAL AT WEEKS												
35-36wks	-	-	2	6.67	-	-	-	-	6	11.3 NS	0.079	12.59
37-38wks	-	-	2	6.67	14	46.67	3	10				
39-40wks	1	3.33	2	6.67	5	16.67	1	3.33				
WEIGHT OF THE BABY												
3.6-4.5 Kg	-	-	1	3.33	4	13.33	-	-	6	0.94 NS	0.98	12.59
4.6-5.5Kg	1	3.33	4	13.33	12	40	3	10				
5.6-6.5 Kg	-	-	1	3.33	3	10	1	3.33				
NAME OF THE VACCINE												
Easy six	1	3.33	5	16.67	13	43.33	4	13.33	3	4.83 NS	0.18	7.81
Penta vac	-	-	1	3.33	6	20	-	-				
DOSAGE OF VACCINE												
I^{st} dose	-	-	1	3.33	2	6.67	-	-	6	6.09 NS	0.41	12.59
II^{nd} dose	-	-	3	10	7	23.33	4	13.33				
III^{rd} dose	1	3.33	2	6.67	10	33.33	-	-				

NS: Non significant

Table 4.6 reveals that none of the above variables had significant association with the level of pain during Intramuscular vaccination. Hence research hypothesis was rejected and accepted null hypothesis.

Table 4.7 Association of selected demographic variable with pain level of infants during intramuscular vaccination in routine group

H_{03}: There will not be a significant association between the pain level of infants and selected demographic variables during intra muscular vaccination **n=30**

Demographic Variables	Routine group								df	Calculated $\chi 2$ value	P value	Tabulated value
	Relaxed		Mild		Moderate		Severe					
	F	%	F	%	F	%	F	%				
AGE												
6 weeks	-	-	-	-	2	6.67	5	16.67				
10weeks	-	-	-	-	1	3.33	12	40	2	3.58 NS	0.16	5.99
14weeks	-	-	-	-	-	-	10	33.33				
GENDER												
Male	-	-	-	-	2	6.67	12	40				3.84
Female	-	-	-	-	1	3.33	15	50	1	6.44**	0.01	
GESTATIONAL AT WEEKS												
35-36wks	-	-	-	-	1	3.33	2	6.67				
37-38wks	-	-	-	-	1	3.33	15	50	2	2.02 NS	0.35	5.99
39-40wks	-	-	-	-	1	3.33	10	33.33				
WEIGHT OF THE BABY												
3.6-4.5 Kg	-	-	-	-	2	6.67	7	23.33				
4.6-5.5Kg	-	-	-	-	1	3.33	11	36.67	2	2.51 NS	0.28	5.99
5.6-6.5 Kg	-	-	-	-	-	-	9	30				
NAME OF THE VACCINE												
Easy six	-	-	-	-	2	6.67	18	60		1.66		
Penta vac	-	-	-	-	1	3.33	9	30	1	NS	0.19	3.84
DOSAGE OF VACCINE												
I^{st} dose	-	-	-	-	2	6.67	5	16.67				
II^{nd} dose	-	-	-	-	1	3.33	12	40	2	3.58 NS	0.16	5.99
III^{rd} dose	-	-	-	-	-	-	10	33.33				

Note- : - Statistically significant ** p<0.01 NS: Non significant

Table 4.7 clarifies that there is a significant association found between gender with the pain level of infants during intramuscular vaccination (p<0.01). It shows that Half of the 15(50%) female infants experienced severe pain compared with male infants 12(40%) in routine group. Hence null hypothesis is partially rejected and research hypothesis is accepted to only in gender. For other demographic variables like age, gestational age at birth, weight of the infants, name of the vaccination, frequency of the vaccination there is no significant association. Hence null hypothesis is accepted and research hypothesis is rejected.

CHAPTER V

RESULTS AND DISCUSSION

This chapter presents a detailed discussion based on the major objectives, corresponding findings and observation during the conduct of the study. The present study was conducted to assess the effectiveness of Helfer skin tap technique on pain reduction among infant undergoing intramuscular vaccination**.** The study finding was compared with the findings and observation of similar studies.

5.1 Frequency and percentage distribution of infants undergoing intramuscular vaccination in treatment and routine group according to demographic variables

The current study result shows that majority of the infants 50(83%) were in age group of 10-14 weeks in routine and treatment group. More than half of the infants 31(51.67 %) were male and about half of the infants 32(53.3%) were weighing between 4.6-5.5kg.

A similar experimental study was conducted among 60 infants, indicated that 50 infants were age group of 10weeks in routine and experimental group. More than half of the infants (58%) were female and 55% of the infants were weighing 4.5kg **(Jose, Rose Mary,2013)**

The present study reveals that more than half of the infant 35 (58.33%) were between the 37-38 weeks of gestational age at birth.

A similar experimental study conducted at lucknow among 100 full term neonates. The study result represent that 37% neonates were 37 weeks of gestational age at birth**.(Maj. Siva priya, Col leena kumari, 2015)**

5.2 Frequency and percentage distribution of various degree of pre and post test FLACC pain score between treatment and routine group.

The present study reveals that the treatment group 27(90%) infants were relaxed and comfortable during preassessment,19(63.33%) infants had moderate pain during vaccination, on post assessment at 1^{st} minute 18(60%) infants had moderate pain ,at 5^{th} minute 15(50%) infants had mild pain and at 10^{th} minute 26(86.6%) infants were relaxed and comfortable. In Routine

group 23 (76.77%) infants were relaxed and comfortable during preassessment,27(90%) infants had severe pain during vaccination, on post assessment at 1st minute 18(60%) infants had moderate pain ,at 5th minute 16(53.33%) infants had mild pain and at 10th minute 24(86.6%) infants had mild pain and 6(20%)infants were relaxed and comfortable.

The result of the above study are similar to an experimental study on effectiveness of Helfer skin tap technique during IM injection among 100 neonates born in labour room the result revealed that 86% neonates in the experimental group had mild pain. Only 14% neonates perceived severe pain during IM injection by using Helfer skin tapping technique ,where as conventional routine group 86% of neonates perceived severe pain ,only 14% of neonates perceived moderate pain**.(Maj.Siva priya, Col leena kumari ,2015)**

5.3 Comparison of pre and post test level of pain among infants undergoing intramuscular vaccination pain in treatment group .

The current study explored that there was a significant reduction in pain perception during vaccination ($t=10.32, p<0.001$), After the vaccination at 1st minute ($t=7.756, p<0.001$) ,5th minute ($t=3.139, p<0.001$). The current study was designed as a pretest and post test design presuming that infants may have anticipatory pain related to procedure and new technique.

Contradically another experimental study on effectiveness of Helfer skin tap technique during IM injection among 100 full term neonates born in labour room clarifies that there was no possibilities to pretest the subject since they adopted post test only design. **(Maj.Siva priya, Col leena kumarai, 2015)**

5.4 Comparison of pain score at various time intervals of intramuscular vaccination pain between treatment and routine group of infants undergoing intramuscular vaccination .

The infants who received Helfer skin tap technique experienced moderate pain (5.30 ± 1.74) and routine group infants experienced severe pain during the vaccination ($8.70 \pm 1.02, p<0.001$).After the vaccination at 1st minute in treatment group infants had mild pain ($3.93 \pm 1.51, p<0.001$) where as in routine group infants had moderate pain (6.83 ± 1.04). Smiliarly, at 5th minute in treatment group infants experienced mild pain($2.03 \pm 1.69, p<0.001$) where as in routine group infants still experienced moderate pain (4.03 ± 1.33) . At 10th minute in treatment

group infants were relaxed and comfortable(0.30 ± 0.79) where as in routine group infants experienced mild pain(1.87 ± 1.17,p<0.001).

The findings of the above study are in line with an experimental study on effectiveness of Helfer skin tap technique during IM injection among 100 full term neonates born in labour room. This study adopted with post test only research design and pain was assessed only during IM injection, which reveals that in experiment group newborn experienced mild pain (2.15±2.01) and control group newborn experienced moderate pain (5.7±0.73) during IM injection. It clarifies that there was a significant decrease in the pain score between the administration of IM injection with Helfer skin tap technique (z=4.003, p<0.001). **(Maj. Siva priya, Col leena kumari, 2015).**

In current study infants pain perception was assessed during and after intramuscular vaccination, which shows that Helfer skin tap technique is effective in reduce the vaccination pain during and after vaccination at 1^{st}, 5^{th},&at 10^{th} minute.

5.5 Association of selected demographic variables with pain level of infants during intramuscular vaccination in treatment and routine group.

The present study shows that a significant association was found between the gender with the pain level of infants during intramuscular vaccination in routine group (p<0.01). It shows that most of the 15(50%) female infants experienced severe pain compared with male infants 12 (40%) in routine group.

A similar experimental study confirms that there was a significant association between the pain score and selected demographic variable like gender & weight (p<0.001). It shows that half of the female infants 20(66.66%) and 18(60%) infants weighing between 4-5kg experienced severe pain in routine group. **(Jose ,Rose Mary,2013).**

CHAPTER VI

SUMMARY AND CONCLUSION

Skin tapping is the most widely used complementary therapy in nursing practice. It is an accepted fact that reducing pain while giving intramuscular vaccination. This Helfer Skin Tap Technique states that mechanical stimulation over the skin can alter the balance between the small diameter fibers' that carry pain to the brain, and the large diameter fibres that do not carry pain. The large diameter non-pain fibers block the small diameter fibers that carrying the pain through the effective skin tap technique **.**The Present study was undertaken to assess the effectiveness of Hellfer skin tap technique on pain reduction among infant undergoing intramuscular vaccination in tertiary care settings, Coimbatore. The main objective is to compare the level of pain in infant during intramuscular vaccination in treatment and routine group as measured by FLACC pain scale. The wide literature search also helped in selection of appropriate conceptual planning, developing frame work and research plan.

The research design used in this study was quantitative research approach, quasi experimental, time series design. The study was conducted in pediatric vaccination clinic in PSG Hospitals, Peelamedu, Coimbatore. Purposive sampling technique was used in this study. Sixty samples were randomly allocated to treatment group to receive the Helfer skin tap technique and routine group to receive the routine care by simple random sampling. The data were collected after ethical approval. FLACC pain scale was used to assess the vaccination pain among infants undergoing intramuscular vaccination. Pre assessment was done before administering IM vaccination in intervention and routine group and Helfer skin tapping was given to infants who belongs to treatment group. Post test level of pain was assessed at 1^{st} minute, 5^{th} minute, and at 10^{th} minute by using FLACC pain scale.

The data was collected through interview and observation for all infants of both treatment and routine group. Descriptive and inferential statistics were used for analyses of the data. Paired't' test was used to compare the pre and post test level of intramuscular vaccination pain among infants undergoing intramuscular vaccination pain in treatment group and routine group. Independent "t" test was used to compare the effectiveness of Helfer skin tap technique in treatment and routine group. Chi square test was used to find out the association between

selected demographic variables with the pain level of infants during intramuscular vaccination among treatment group and routine group.

6.1 Major finding of the study:

- Among 60 infants more than half of the infants 50(83%) were age group of 10-14 weeks in routine and treatment group
- Among 60 infants 31(51.67%) infants were male
- Out of 60 infants more than half of the infants 35(58.34%) were in between the 37-38 weeks of gestation age at birth.
- More than half of the infants 32(53.33%) were weighing between 4.6-5.5kg
- Majority of the infants 43(71.67%) had easy six vaccination.
- Less than half of the infants 27(45%) had IInd dose of vaccination.
- Among treatment group who received Helfer skin tap technique infants experienced moderate pain during vaccination (5.30±1.74,p<0.001),mild pain after 1st (3.93±1.51,p<0.001) &5th minute (2.03±1.69,p<0.001) and no pain (0.39±0.79, p<0.001) at 10th minute.
- Among routine group who received the routine care, the infants experienced severe pain during vaccination (8.70±0.2,p<0.001) , moderate pain after 1st (6.43±1,p<0.001)&5th minute (4.03±1.33,p<0.001) and mild pain (1.87±1.17,p<0.001)at 1^{0th} minute.
- There was no association between selected demographic variables with pain level of infants in during IM vaccination except gender in routine group. Only female infants 15(50%) in the routine care group experienced severe pain during intramuscular vaccination (χ^2=6.44, p<0.01).

6.2 Conclusion:

Vaccination pain is a major source of distress for children and their families as well as health care providers. Tapping over the skin is one of the complimentary techniques to keep the muscles relaxed. It is an accepted fact that pain reduction will occur while giving injection with Helfer skin tap technique.

This study finding demonstrate that Helfer skin technique is one of the most effective method for pain reduction during intra muscular vaccination .This technique can be adopted during vaccination among infants as non pharmacological therapy in the management of pain.

6.3 Nursing implications:

The present study has implications for nursing practice, nursing education, nursing administration and nursing research.

6.3.1 Nursing practice:

- Nurse has to be trained in applying Helfer skin tap technique on pain reduction among infants undergoing intramuscular vaccination in clinical and community settings.
- Emphasis the nurses to use FLACC Pain scale in their daily practice in order to assess the pain of infants during vaccination.

6.3.2 Nursing education:

- Non pharmacological measures of Helfer skin tap technique can also be included in the nursing curriculum.
- Organizing Continuing education for staff nurses will help to promote and update their knowledge on usage of Helfer skin tap technique on pain reduction among infant undergoing intramuscular vaccination

6.3.3 Nursing administration:

- Provision should be made for the staff working in vaccination clinic to get training in regular usage of non pharmacological measures.
- Nursing administrators can motivate nurses to use Helfer skin tap technique in their clinical practice among Infants under going intramuscular vaccination by ongoing training.
- The protocol of administration of IM vaccine can be reframed with the Helfer Skin Tap Technique.

6.3.4 Nursing research:

- Nurse researcher can conduct studies to verify the scientific principle and physiology behind the effect of skin tapping on Intramuscular vaccination pain reduction.
- Randomized clinical trials could be under taken so that the validity of the results can be increased and it can be incorporated into the evidence based nursing practice**.**

6.4 Limitation

- The vaccination pain may have been varied according to technique of vaccination and skill of the nurse in administering the IM vaccine.
- Generalization cannot be made due to limited area of setting and limited sample size

6.5 Recommendation for furthers study:

- The similar study can be conducted in large group of population.
- The similar study can be conducted in all age group of children.
- A study to can be conducted to assess the effectiveness of Helfer skin tap technique on pain reduction among children undergoing various type of vaccination.

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ANNEXURE-I

From

Ms. Menaka.J
M. Sc Nursing I Year
PSG College of Nursing
Peelamedu, Coimbatore - 04

To

The HOD of pediatric Department

PSG Hospital

Coimbatore-04

Through The principal ,PSG college of Nursing

Respected Sir ,

Sub: Seeking permission to carry out the study among Children Attending vaccination clinic at PSG Hospitals, Coimbatore.

I Ms. Menaka.J, I year M. Sc Nursing student is interested in doing this study. **"A Study To Assess The Effectiveness of Helfer Skin Tap Technique On Pain Reduction Among Infants Undergoing Intramuscular Vaccination In Tertiary Care Setting , Coimbatore".** Kindly grant me permission to carry out the study .

Thanking you,

Date:

Place:

Yours sincerely

Ms.J.Menaka
I year M. Sc Nursing

19.7.17

Signature of the HOD of Pediatric Department.

PSG COLLEGE OF NURSING, COIMBATORE-4.

Ref.No: CN/I/103/17 Date: 04.07.2017

To

The Dean
PSG IMSR&H
Peelamedu
Coimbatore.

Respected Sir,

Sub: Permission to conduct research req.reg

Warm Greetings!

This is to inform you that Ms. Menaka. J, I year M.Sc Nursing student of our College of Nursing, Coimbatore is planning to conduct a study on

"A Study to Assess the Effectiveness of Helfer Skin Tap Technique on Pain Reduction among Infants Undergoing Intramuscular Vaccination in a Tertiary Care Settings, Coimbatore"

as part of M.Sc(N) research requirement to be submitted at The Tamilnadu Dr. M.G.R Medical University, Chennai.

Kindly grant permission for conducting pilot & Main study in our Hospital (Vaccination Room). We assure you that the study will be conducted without disturbing the routine activities of the Hospital.

Thanking you,

4/7/17

Dr. A. JAYASUDHA
PRINCIPAL

PSG COLLEGE OF NURSING Peelamedu COIMBATORE-4

Ok. May with ethics approval

Cc to: The Nursing Superintendent

ANNEXURE II

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

Ms Menaka J
I M Sc Nursing
Guide/s: Mrs Glory H / Dr G Malarvizhi
PSG College of Nursing
Coimbatore

Ref: Project No.17/234

Date: August 17, 2017

Dear Ms Menaka,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 21.07.2017 to conduct the research study entitled "*A study to assess the effectiveness of Helfer skin tap technique on pain reduction among infant undergoing intramuscular vaccination in tertiary care settings*" during the IHEC meeting held on 11.08.2017.

The following documents were reviewed and approved:

1. Project submission form
2. Study protocol (Version 1 dated 21.07.2017)
3. Parental consent forms (Version 1 dated 21.07.2017)
4. Data collection tool (Version 1 dated 21.07.2017)
5. Permission letter from the Dean and concerned Head of the Department
6. Current CVs of Principal investigator, Co-investigator
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 11.08.2017 at IHEC Secretariat, PSG IMS & R between 10.00 am and 11.00 am:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Mr R Nandakumar (Chairperson, IHEC)	BA., BL	Legal Expert	Male	No	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
3	Dr S Shanthakumari	MD	Pathology	Female	Yes	Yes
4	Dr Sudha Ramalingam	MD	Epidemiologist Alt. member-Secretary	Female	Yes	Yes
5	Dr D Vijaya	M Sc., Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee

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Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
   a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
   b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
   c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
   d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
   e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
   f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,

SECRETARY
PSG IMS&R
COIMBATORE-641004.

Dr S Bhuvaneshwari
Member - Secretary
Institutional Human Ethics Committee

ANNEXURE III

SOP 03-V 3.0 / ANX 10-V 3.0

Institutional Human Ethics Committee
PSG Institute of Medical Sciences and Research, Coimbatore

Parental Consent Form

Title of Study: A Study to Assess The Effectiveness of Helfer Skin Tap Technique On Pain Reduction Among Infant Undergoing Intramuscular Vaccination in Tertiary Care Settings, Coimbatore.

Name of the Principal Investigator: Ms.Menaka.J

Department: M.sc Nursing I Year Child Health Nursing Department.

Your (son/daughter/child/infant/adolescent youth) is invited to participate in a Study of Assess The Effectiveness of Helfer Skin Tap Technique On Pain Reduction Among Infant Undergoing Intramuscular Vaccination in Tertiary Care Setting, Coimbatore.

My name is Ms.Menaka.J and I am a M.sc Nursing I Year Student at PSG Institute of Medical Science and Research , Coimbatore. This study is part of my partial fulfillment of M.sc Nursing Program.

I am asking for permission to include your (son/daughter/child/infant/adolescent youth) in this study because Injection for vaccination is the most common source of iatrogenic pain in childhood. It is administered repeatedly to almost all children through out infancy, child hood and adolescence. The pain associate with such injections is a source of distress for children , their parents and those administering the injection. Hence the effective helfer skin tap technique will help to reduction of pain.

I expect to have 60 Infants in the study, who undergone Intramuscular Vaccination ,and who fulfill inclusion criteria from PSG Hospital, Vaccination Room.

If you will allow your child to participate , In this study, as a principle investigator I am going to apply helfer skin tap technique to your child before and during vaccination and to observe the pain level through video record. And intensity of the pain will be assess through the FLACC Pain Scale

Any information that is obtained in connection with this study and that can be identified with your(son/daughter/child/infant/adolescent youth) will remain confidential and will be disclosed only with your permission. His or her responses will not be linked to his or her name or your name in any written or verbal report of this research project.

Your decision to allow your (son/daughter/child/infant/adolescent youth) to participate will not affect your or his or her present or future relationship with PSGIMS&R or PSG Hospitals . If you have any questions about the study, please ask me. If you have any questions later, call me at any time. If you have any questions or concerns about your infant's participation in this study, call 8189974544

You may keep a copy of this consent form.

You are making a decision about allowing your infant to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow him or her to participate in the study. If you later decide that you wish to withdraw your permission for your infant to participate in the study, simply tell me.

You may discontinue his or her participation at any time. *This will not affect in any way your future treatment in this hospital.*

Printed Name of (son/daughter/child/infant/adolescent youth)

Signature of Parent(s) or Legal Guardian with Date: Signature of Investigator with Date:

பூ சா கோ மருத்துவக் கல்லூரி மற்றும் ஆராய்ச்சி நிறுவனம். கோவை

மனித நெறிமுறைக் குழு

பெற்றோர் ஒப்புதல் படிவம்

ஆய்வின் தலைப்பு: தசையூடாக தடுப்பூசி போடும் போது குழந்தைகளுக்கு ஏற்படும் வலியின் தன்மையை தொடைத் தசைபகுதியை தட்டிக்கொடுக்கும் உதவி முறையின் மூலம் வலியை குறைப்பது என்பதைப் பற்றிய ஆய்வு.

ஆய்வளரின் பெயர்: ஜெ.மேனகா

பிரிவு: குழந்தைகள் நலப் பிரிவு

நான் தங்களின் குழந்தையை தசையூடாக தடுப்பூசி போடும் போது குழந்தைகளுக்கு ஏற்படும் வலியின் தன்மையை தொடைத் தசைபகுதியை தட்டிக்கொடுக்கும் உதவி முறையின் மூலம் வலியை குறைப்பது என்ற ஆய்விற்கு ஆய்வு மாதிரியாக உட்படுத்த தங்களின் ஒத்துழைப்பை வேண்டுகிறேன்

ஜெ.மேனகா ஆகிய நான் பூ.சா.கோ செவிலியர் கல்லூரியில் குழந்தைகள் நல பிரிவு துறையின் கீழ் முதுநிலை செவிலியர் பட்டப்படிப்பு படிக்கிறேன்..

நான் இந்த ஆய்விற்காக தங்களின் அனுமதியை வேண்டுகிறேன் ஏனெனில் பொதுவாக குழந்தைகளுக்கு தடுப்பூசி போடுவதனால் ஏற்படும் வலியானது தவிர்க்கமுடியாத ஒன்றாகும். தொடர்ந்து தடுப்பூசியானது குழந்தைப்பருவம் முதல் இளமைப்பருவம் வரை கொடுக்கப்பட்டுவருகிறது. இதனால் ஏற்படும் வலியானது குழந்தை மற்றும் பெற்றோர்களின் மத்தியில் அசௌகரியங்களை ஏற்படுத்துகிறது. ஆதலால் தடுப்பூசி கொடுக்கும் பொழுது தொடை தசைப் பகுதியை தட்டிக்கொடுக்கும் உதவி முறையின் மூலம் வலியைக் குறைக்கலாம்.

பூ சா கோ மருத்துவ மருத்துவமனையின் தடுப்பூசி அறையில் ஐந்து மற்றும் ஆறு விதமான தடுப்பூசிகளும் ஓரே தடுப்பூசியாக (பெண்டா மற்றும் ஈசி சிக்ஸ் தடுப்பூசி) போட வரும் குழந்தைகளில் ஆய்வில் பங்குபெறுவதற்கான நிபந்தனைகளில் நிறைவு செய்யப்பட்ட 60 குழந்தைகள் மட்டும் ஆய்வில் ஈடுபடுத்த படுவார்கள்.

தங்கள் இந்த ஆய்விற்காக தங்களின் ஒத்துழைப்பை அளிக்கும் பட்சத்தில், இந்த ஆய்வின் தொடக்கத்தில் நான் தங்கள் குழந்தையின் அடிப்படைத் தகவல்களை சேகரிப்பேன். முதலில் குழந்தையின் செயல் திறன் கண்காணிக்கப்பட்டு, தடுப்பூசி போடுவதற்கு முன்பும் தடுப்பூசி கொடுக்கும் பொழுதும் தொடை தசைப் பகுதியானது தட்டிக்கொடுக்கப்படும் மேலும் வலியின் தன்மை கானொலி(வீடியோ) மூலம் பதிவு செய்யப்பட்டு முகம், கால், செயல்திறன், அழுகை ,கட்டுப்பாடு, என்ற அளவுகோளைக் கொண்டு ஆய்வு செய்யப்படும்.

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ஆய்வில் பங்குபெறுவதால் எற்படும் அசௌகரியங்கள் / பக்கவிளைவுகள் : ஏதுமில்லை..

இந்த ஆய்வின் கேள்விகளுக்கு பதிலளிப்பதில் உங்களுக்கு ஏதெனும் அசௌகரியங்கள் இருந்தால், எந்த நேரம் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு. ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு எந்த வித பாதிப்பும் இருக்காது என்று உறுதியளிக்கிறோம்.. நீங்கள் அளிக்கப்படும் தகவல்கள் இரகசியமாக வைக்கப்படும். இந்த ஆய்வில் பங்கேற்பவர்கள் பற்றிய எந்தத் தகவலும் எக்காரணம் கொண்டும் வெளியிடப்படாது என்று உறுதியளிக்கிறோம். நீங்கள் அளிக்கப்படும் தகவல்கள் அங்கீகரிக்கப்பட்ட ஆய்விற்கு மட்டுமே பயன்படுத்தப்படும். உங்களுக்கு ஏதேனும் இந்த ஆய்வினைப் பற்றிய சந்தேகம் அல்லது கேள்விகள் இருப்பின் உடனடியாகவோ அல்லது தொலைப்பேசி மூலமோ தொடர்பு கொள்ளவும் - (8189974544)

இந்த ஆய்வைப் பற்றிய மேற்கூறிய தகவல்களை நான் படித்து அறிந்துகொண்டேன் / ஆய்வாளர் படிக்க கேட்டுத் தெரிந்துகொண்டேன். ஆய்வினைப் பற்றி நன்றாகப் புரிந்து கொண்டு இந்த ஆய்வில் என் குழந்தையை ஈடுபடுத்த ஒப்புக் கொள்கிறேன். இந்த ஆய்வில் பங்கேற்பதற்கான எனது ஒப்புதலை கீழே கையொப்பமிட்டு / கைரேகை பதித்து தெரிவித்துக் கொள்கிறேன்.

குழந்தையின் பெயர்;

பங்கேற்பாளரின் பெற்றோரின் கையொப்பம் / கைரேகை / சட்ட பூர்வ பிரதிநிதியின் கையொப்பம் :

ஆய்வாளரின் கையொப்பம் :

ANNEXURE IV.A

SECTION: DEMOGRAPHIC DATA

1) Sample number:
2) Age of the child:
   - □ 6 weeks
   - □ 10 weeks
   - □ 14 weeks
3) Gender:
   - □ Male
   - □ Female
4) Gestational age at birth:
   - □ 35-36wks
   - □ 37-38wks
   - □ 39-40wks
5) Weight of the baby:
   - □ 3.6-4.5kg
   - □ 4.6-5.5kg
   - □ 5.6-6.5kg
6) Name of the vaccine
   - □ Easy six
   - □ Penta vac
7) Frequency of vaccination:
   - □ I Dose
   - □ II Dose
   - □ III Dose

ANNEXURE IV.B

SECTION B- FLACC SCALE:

BEHAVIOUR	Before (5minutes)	During	After		
			1st minute	5th minute	10th minute
FACE 0-No particular expression or smile. 1-occassional grimace or frown, withdrawn, disinterested. 2-frequent to constant quivering chin, clenched jaw.					
LEGS O-Normal position or relaxed 1-Un easy, restless, tense 2-kicking or legs drawn up					
ACTIVITY 0-Lying quietly ,normal position ,moves easily 1-squirming,shifting,back and forth, tense 2-Arched, rigid or jerking					
CRY 0-No cry(awake or sleep) 1-Moans or whimpers: occasional complaint 2- Crying steadily, screams, sobs, Frequent complaints					
CONSOLABILITY 0-Content,relaxed 1-Reassured by touching, hugging or being talked to distractible 2-Diffucult to console or comfort					

INTERPRETATION:

- 0-Relaxed and comfortable
- 1-3-Mild pain
- 4-6-moderate pain
- 7-10-severe pain

ANNEXURE V

A Study to Assess the Effectiveness of Helfer Skin Tap Technique on Pain Reduction Among Infants Undergoing Intramuscular Vaccination in Tertiary Care Setting, Coimbatore.

A brief introduction on Helfer skin tap technique will be given to the parents and relatives with adequate positive reinforcement. Helfer skin tap technique is helps to reduce the vaccination pain among infants undergoing Intramuscular vaccination.

Intervention:

Helfer skin tap technique: Tapping over the intramuscular injection site with the palmer aspect of finger 16 times before and the 3 counts during the intramuscular vaccination and continue the tapping till needle was removed

Steps of Helfer skin tap technique

- Infants were identified as per inclusion criteria
- Infants were placed in supine position
- 5 minutes prior to intervention, the infants were assessed by using FLACC pain scale.
- After identified the intramuscular vaccination site, the vaccination site was tapped 16 times approximately 10 seconds before intramuscular vaccination with the palmer aspect of the dominant hand to relax the muscle.
- During the vaccination, the researcher tapped near the vaccination site 3 times when the vaccination given by nurses.
- Continue tapping near the vaccination site till the needle was removed.
- Assess the pain level during intramuscular vaccination using full video.
- After the vaccination the pain level is assessed at 1^{st} minute, 5^{th} minute and 10^{th} minute using FLACC scale.

ANNEXURE VI

MASTER CODING SHEET

TREATMENT GROUP

	AGE			GENDER		GA AT BIRTH			WEIGHT			NAME OF VACCINE		FREQUENCY OF VACCINE		
SAMPLE	6WKS	10WKS	14WKS	MALE	FEMALE	35-36KS	37-38WKS	39-40WKS	3.6-4.5Kg	4.6-5.5Kg	5.6-6.5kg	EASY SIX	PENTA	1st DOSE	2nd DOSE	3rd DOSE
1	0	0	1	1	0	0	0	1	0	0	1	1	0	0	0	1
2	0	0	1	1	0	0	0	1	0	1	0	1	0	0	0	1
3	0	1	0	1	0	0	1	0	1	0	0	0	1	0	0	0
4	0	0	1	1	0	0	0	1	0	1	0	1	0	0	0	1
5	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	1
6	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	1
7	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	1
8	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	1
9	1	0	0	0	1	0	1	0	1	0	0	1	0	1	0	0
10	0	0	1	1	0	0	0	1	0	1	0	1	0	0	0	1
11	0	0	1	1	0	0	0	1	0	1	0	0	1	0	0	1
12	0	1	0	0	1	0	1	0	1	0	0	1	0	0	1	0
13	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	0
14	0	1	0	0	1	1	0	0	0	0	0	1	0	0	1	0
15	0	0	1	1	0	0	1	0	0	0	1	1	0	0	0	1
16	0	1	0	1	0	0	1	0	0	1	0	1	0	0	1	0
17	1	0	0	1	0	0	1	0	1	0	0	1	0	1	0	0
18	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
19	0	0	1	1	0	0	0	1	0	0	1	1	0	0	0	1
20	0	1	0	1	0	0	1	0	0	1	0	1	0	0	1	0
21	0	1	0	1	0	0	0	1	0	0	1	1	0	0	1	0
22	1	0	0	1	0	1	0	0	1	0	0	1	0	1	0	0
23	0	1	0	1	0	0	1	0	0	1	0	1	0	0	1	0
24	0	1	0	1	0	0	1	0	0	1	0	1	0	0	1	0
25	0	0	1	1	0	0	0	1	0	0	1	1	0	0	0	1
26	0	1	0	0	1	0	0	1	0	1	0	1	0	0	1	0
27	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
28	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
29	0	1	0	1	0	0	1	0	0	1	0	1	0	0	1	0
30	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
								ROUTINE GROUP								
1	0	0	1	1	0	0	0	1	0	0	1	0	1	0	0	1
2	0	0	1	0	1	0	1	0	0	0	1	1	0	0	0	1
3	1	0	0	1	0	0	1	0	1	0	0	1	0	1	1	0
4	0	0	1	1	0	1	0	0	0	0	1	1	0	0	0	1
5	0	1	0	1	0	0	1	0	0	1	0	0	1	0	0	0
6	1	0	0	1	0	0	1	0	1	0	0	1	0	1	1	0
7	1	0	0	0	1	0	0	1	1	0	0	1	0	1	1	0
8	0	0	1	0	1	0	1	0	0	0	1	0	1	0	0	1
9	1	0	0	1	0	0	1	0	1	0	0	0	1	1	1	0
10	0	0	1	1	0	0	1	0	0	0	1	1	0	0	0	1
11	1	0	0	1	0	1	0	0	1	0	0	0	1	1	0	0
12	0	0	1	1	0	0	0	1	0	0	1	0	1	0	0	1
13	0	0	1	0	1	0	1	0	0	1	0	1	0	0	0	1
14	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
15	0	0	1	1	0	0	1	0	0	0	1	0	1	0	0	1
16	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
17	0	1	0	1	0	0	0	1	0	1	0	1	0	0	1	0
18	0	1	0	0	1	1	0	0	0	1	0	1	0	0	1	0
19	0	0	1	0	1	0	0	1	0	0	1	1	0	0	0	1
20	0	1	0	1	0	0	1	0	1	0	0	1	0	0	1	0
21	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
22	0	1	0	1	0	0	1	0	0	1	0	0	1	0	1	0
23	0	1	0	0	1	0	0	1	0	1	0	1	0	0	1	0
24	0	1	0	0	1	0	1	0	0	1	0	1	0	0	1	0
25	0	1	0	0	1	0	0	1	0	1	0	1	0	0	1	0
26	1	0	0	1	0	0	1	0	1	0	0	0	1	1	0	0
27	0	0	1	0	1	0	0	1	0	0	1	1	0	0	0	1
28	0	1	0	0	1	0	0	1	0	1	0	0	1	0	1	0
29	0	1	0	0	1	0	0	1	1	0	0	1	0	0	1	0
30	1	0	0	0	1	0	0	1	1	0	0	1	0	1	0	0